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Sharma

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(54) **RATE RESPONSIVE PACING**

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A61N 1/365 (2006.01)
A61N 1/05 (2006.01)
A61N 1/368 (2006.01)

(52) **U.S. Cl.**

CPC *A61N 1/36542* (2013.01); *A61N 1/3655* (2013.01); *A61N 1/36507* (2013.01); *A61N 1/36521* (2013.01); *A61N 1/36564* (2013.01); *A61N 1/36571* (2013.01); *A61N 1/36578* (2013.01); *A61N 1/36585* (2013.01); *A61N 1/056* (2013.01); *A61N 1/3684* (2013.01)

(58) **Field of Classification Search**

None
See application file for complete search history.

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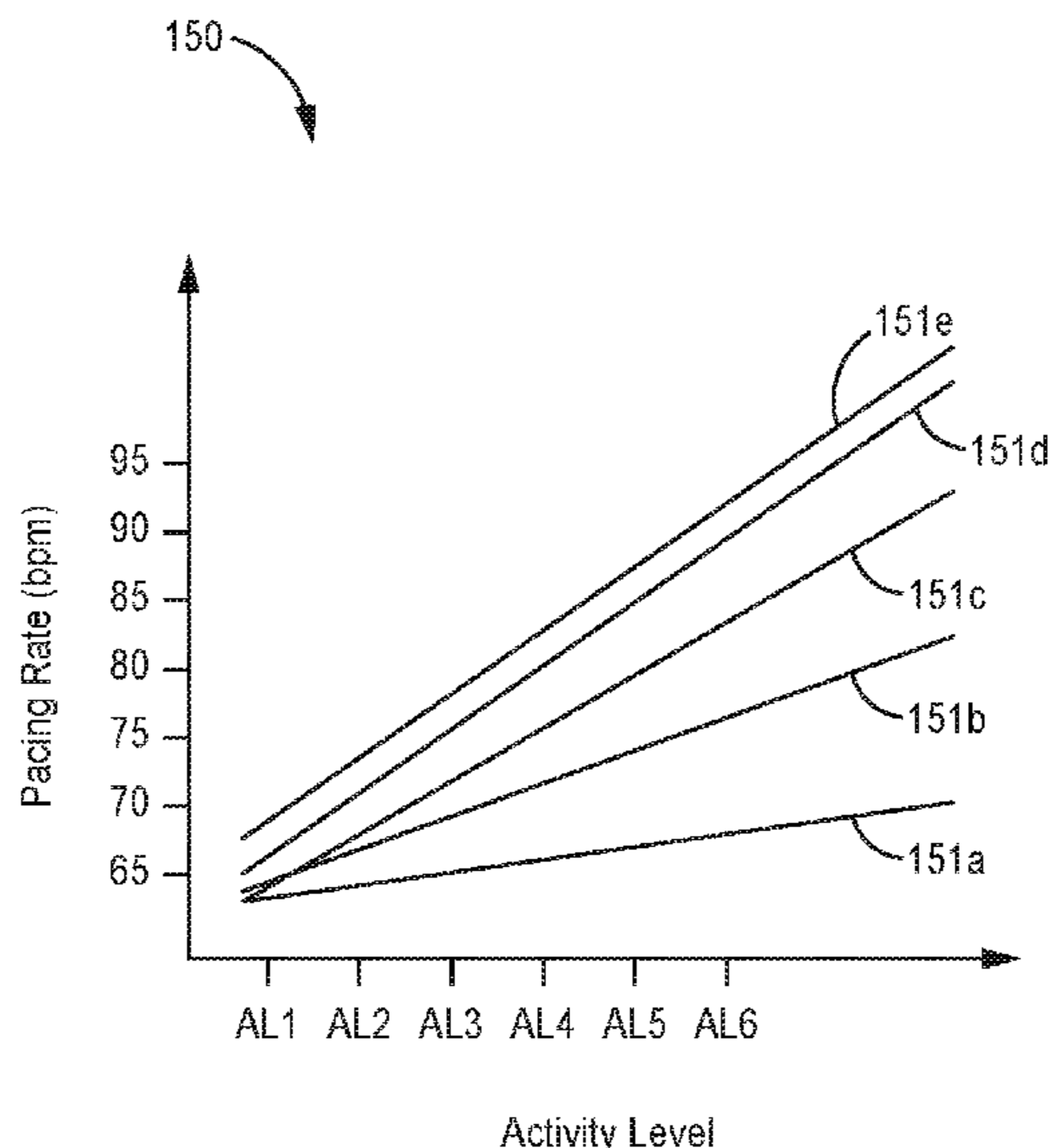
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(57) **ABSTRACT**

Some aspects relate to systems, devices, and methods of delivering rate responsive pacing therapy. The method includes monitoring activity information related to an activity level of a patient and delivering rate responsive pacing (RRP) to the patient at a pacing rate corresponding to a RRP profile. The RRP profile may be used to generate the pacing rate based on the activity information and may be adjusted based on the monitored activity information.

16 Claims, 9 Drawing Sheets



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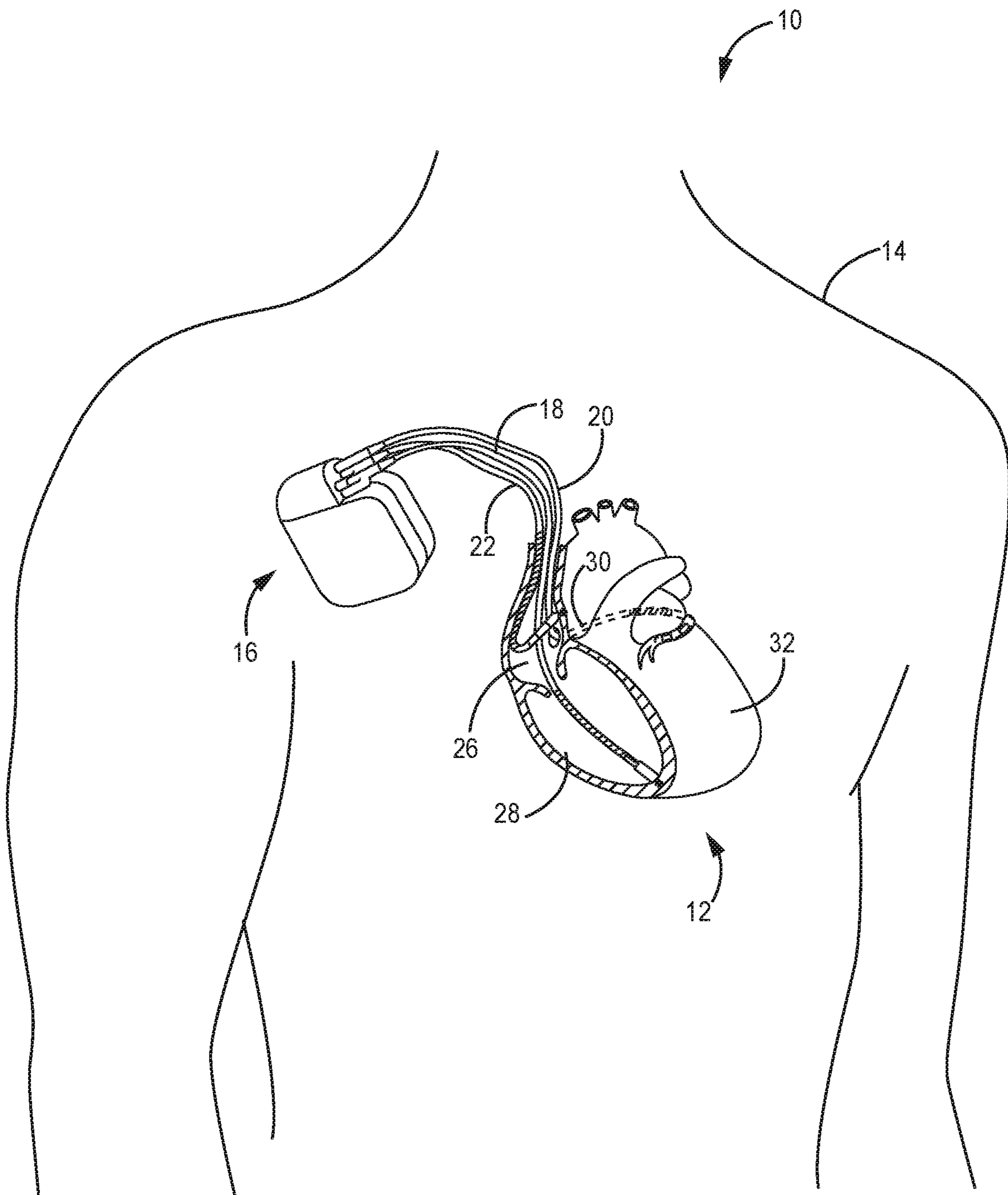


FIG. 1

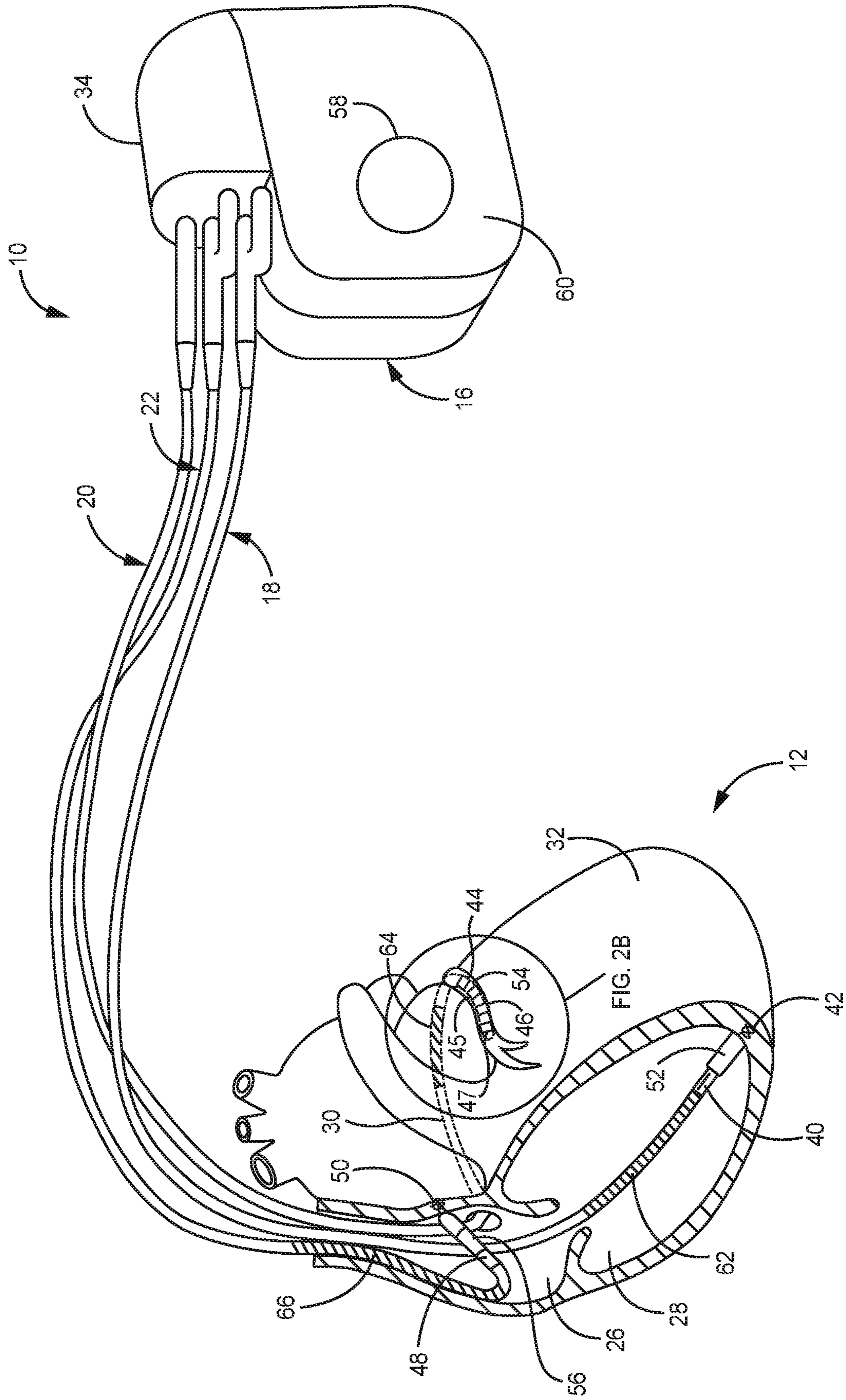


FIG. 2A

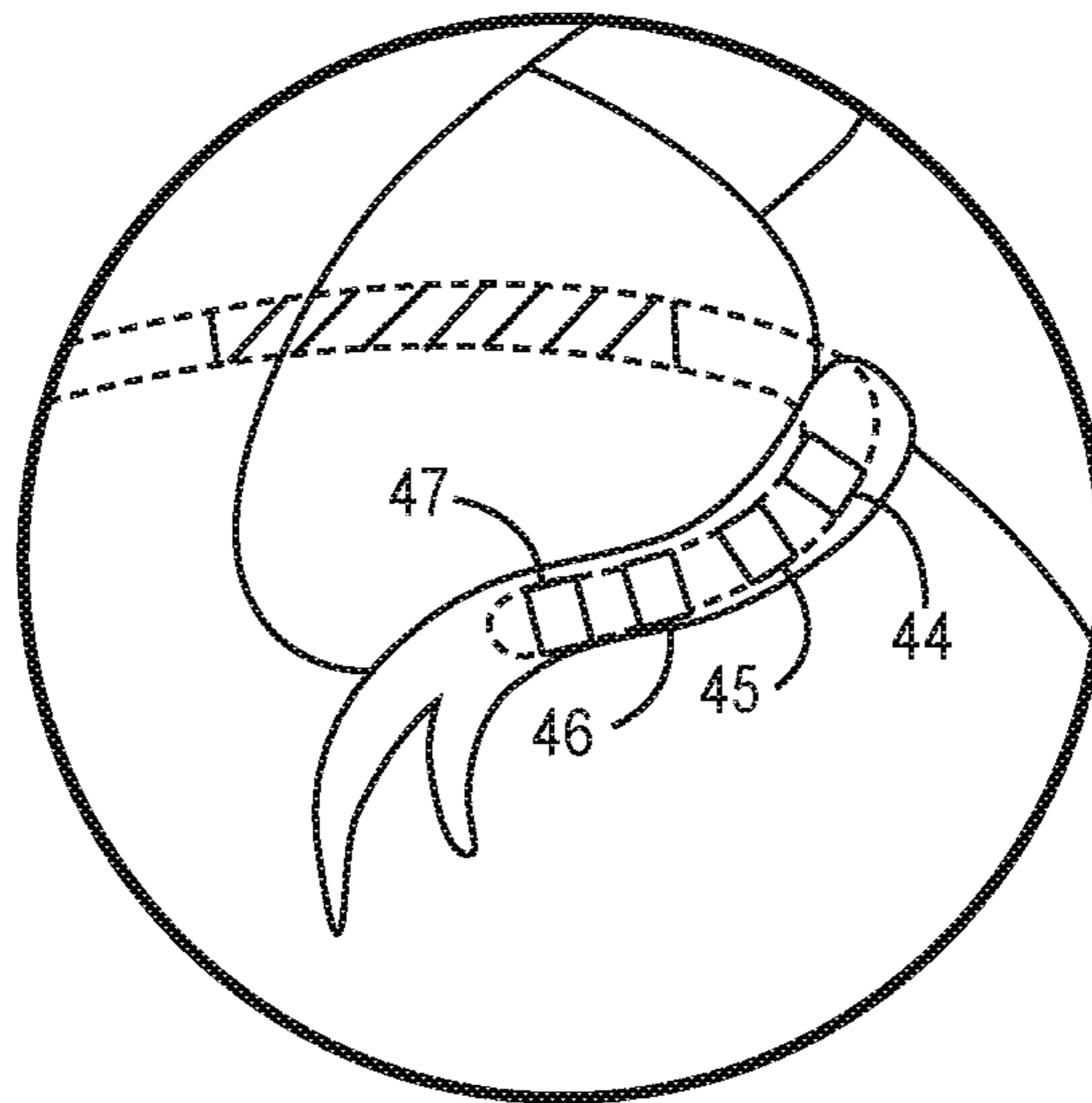


FIG. 2B

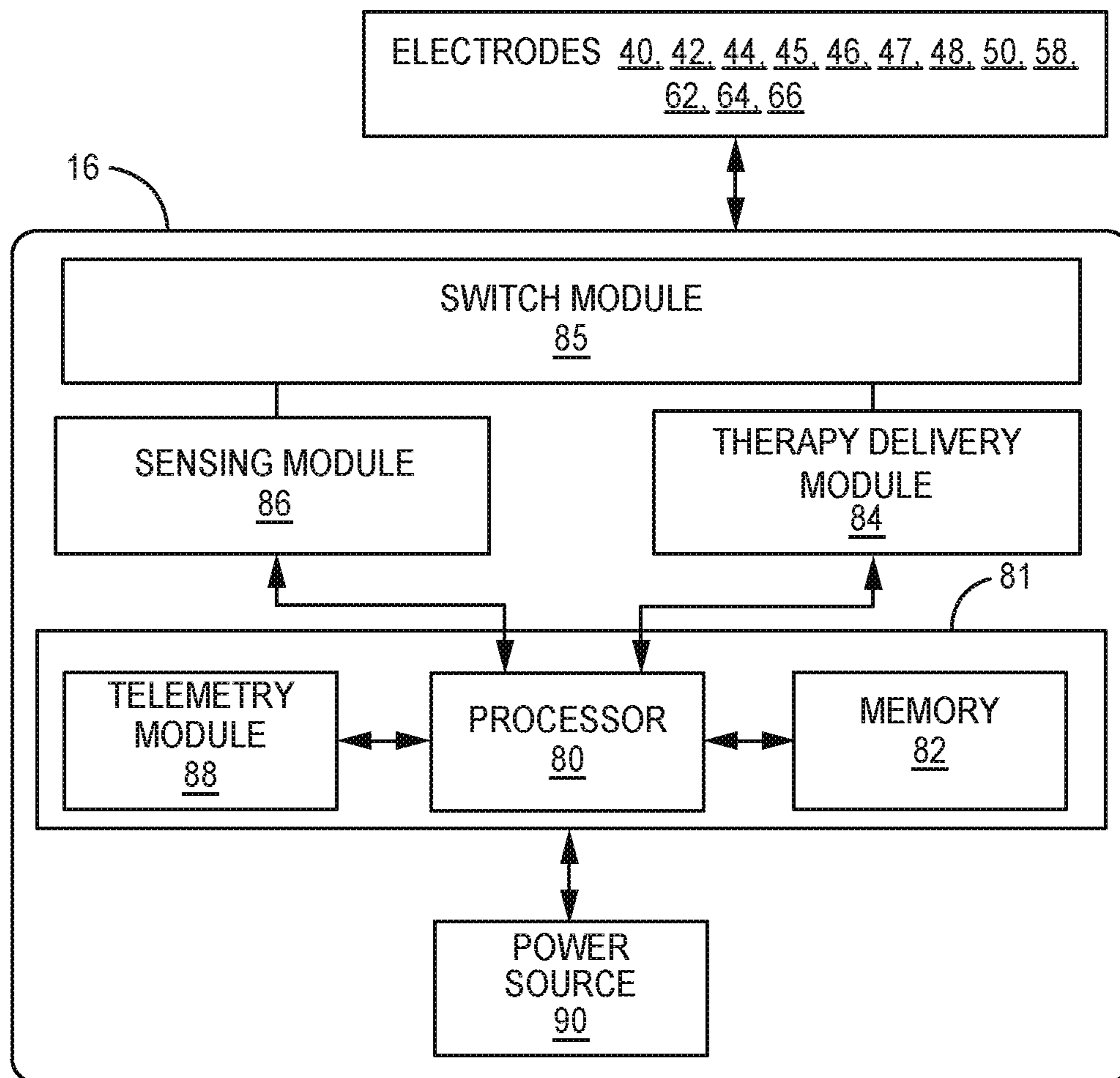


FIG. 3A

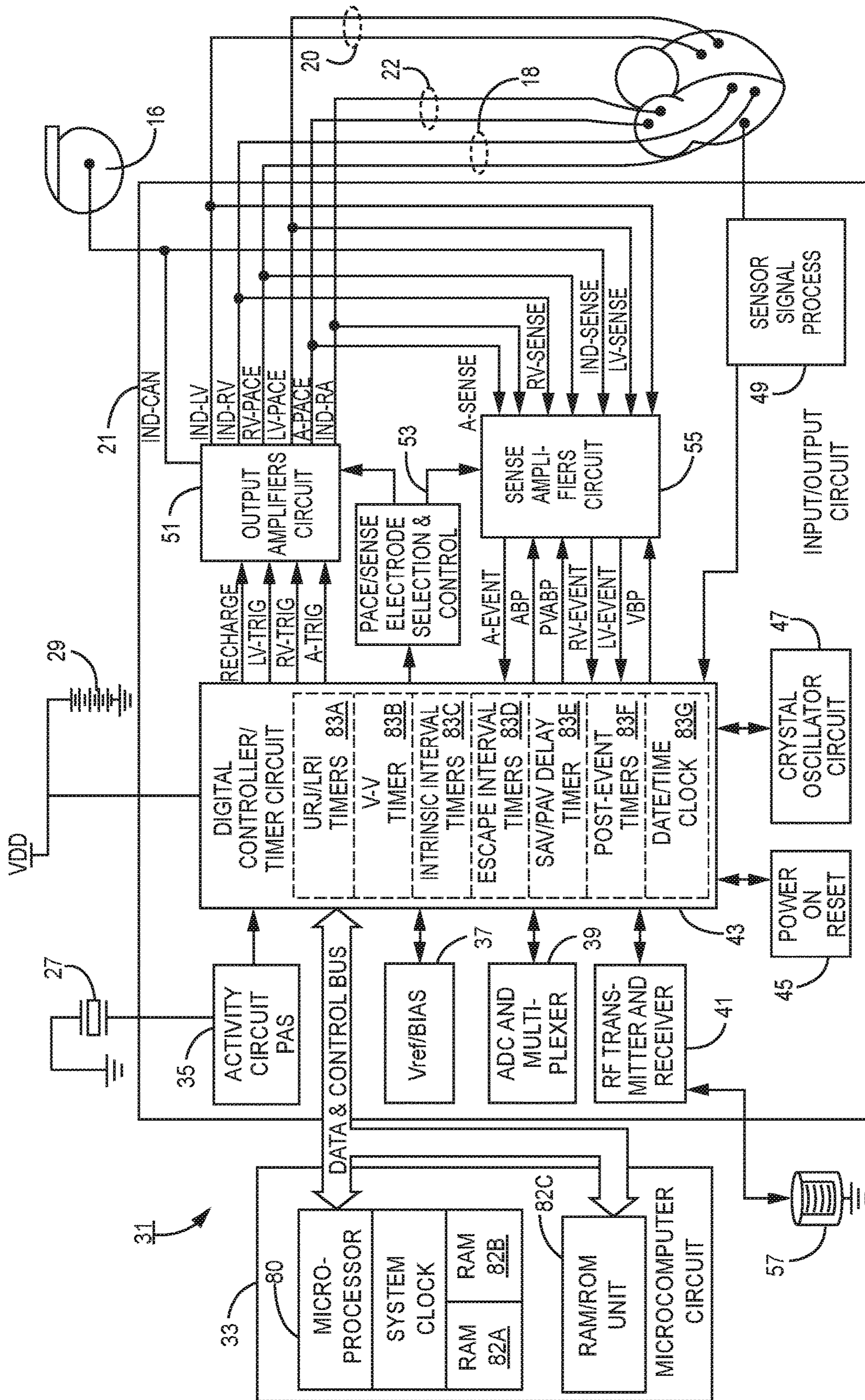


FIG. 3B

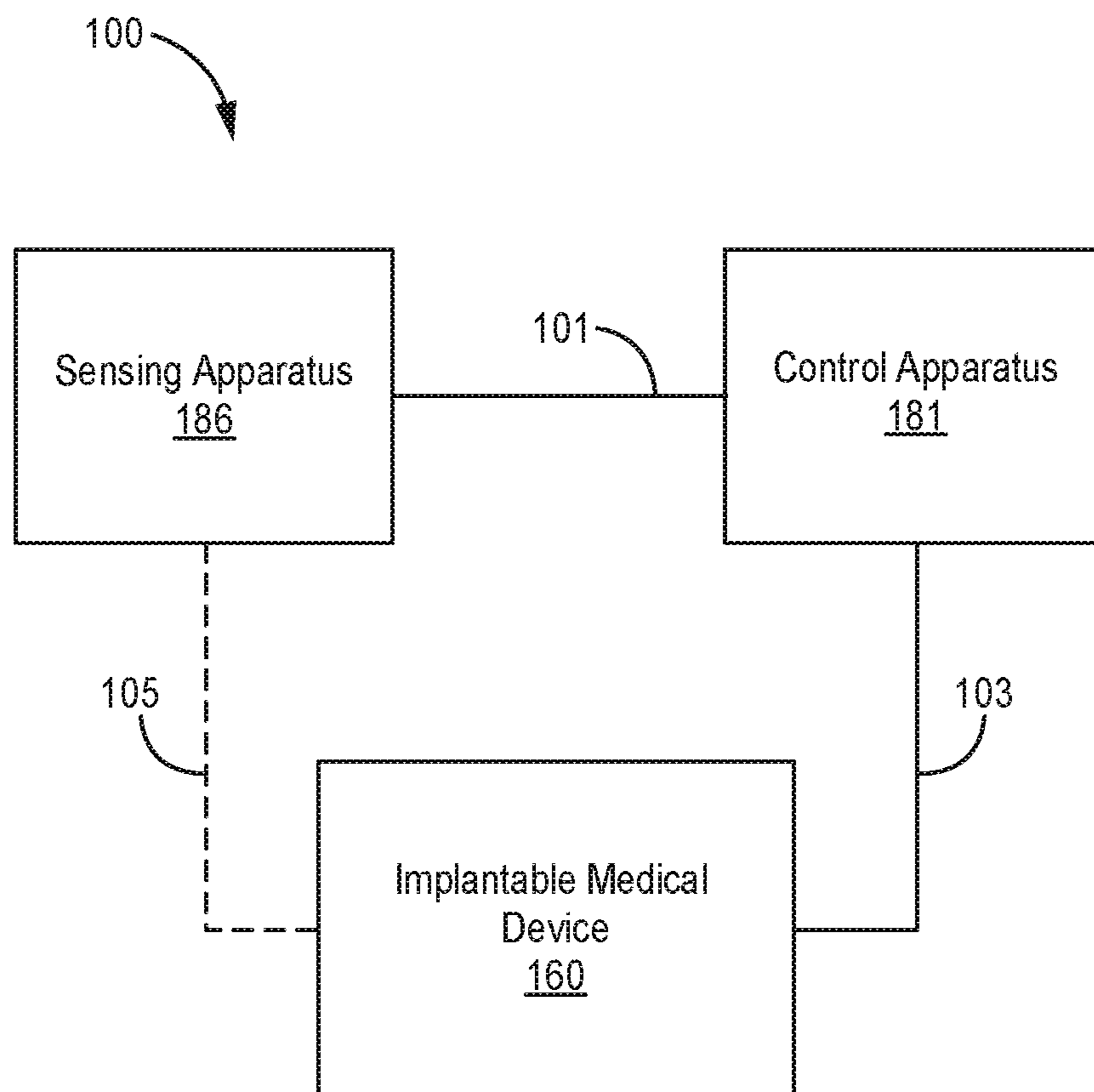


FIG. 4

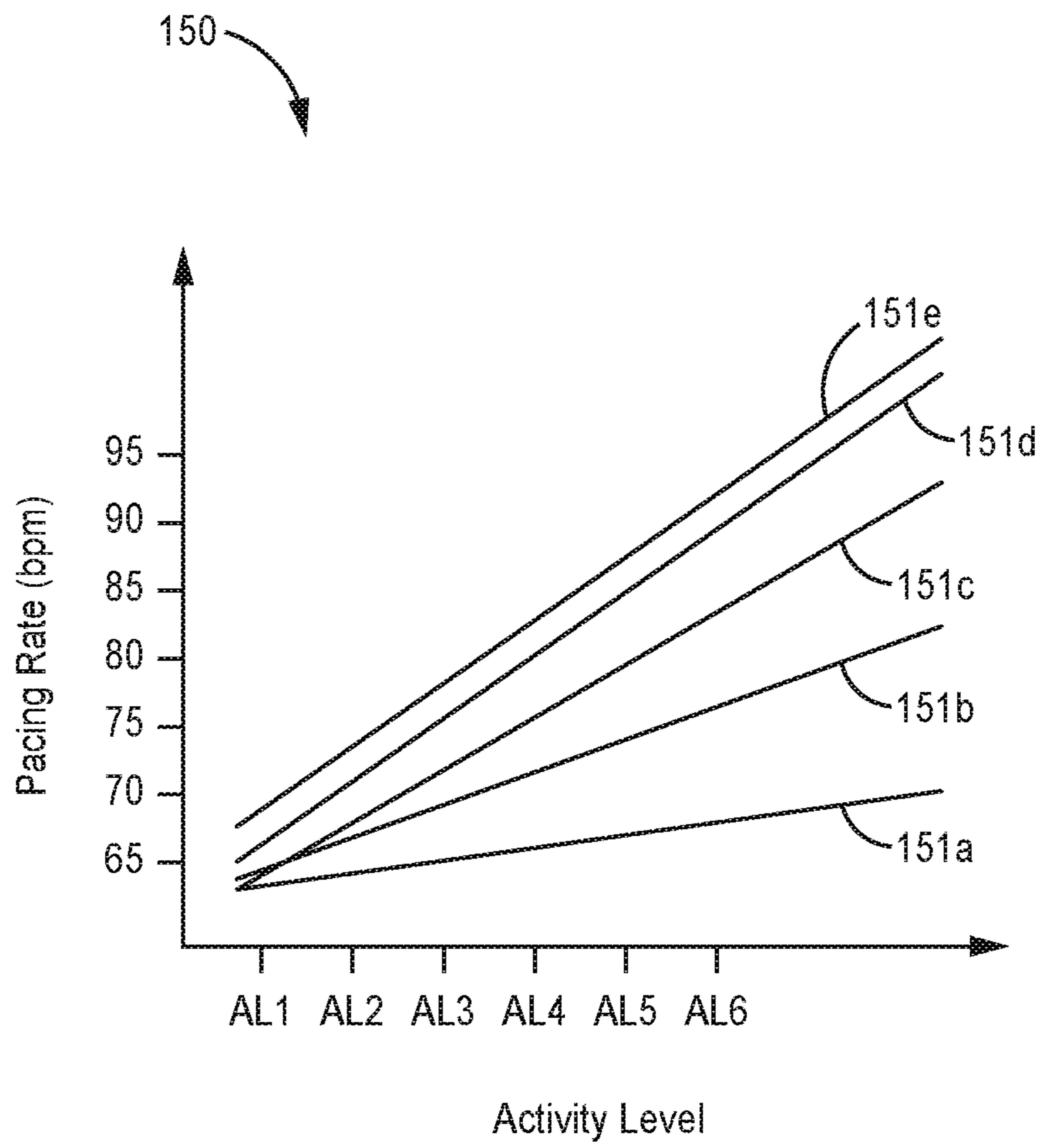


FIG. 5

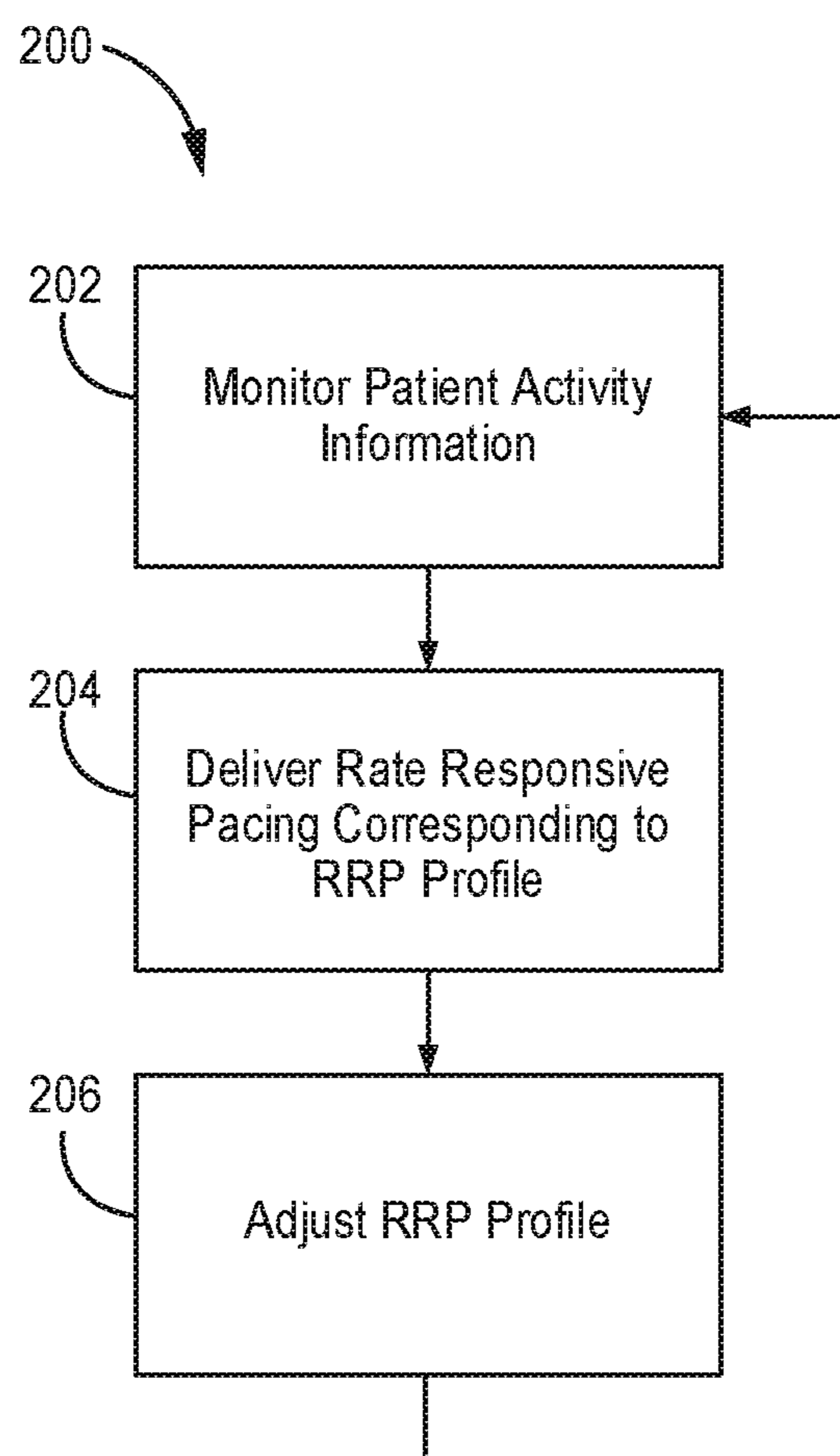


FIG. 6

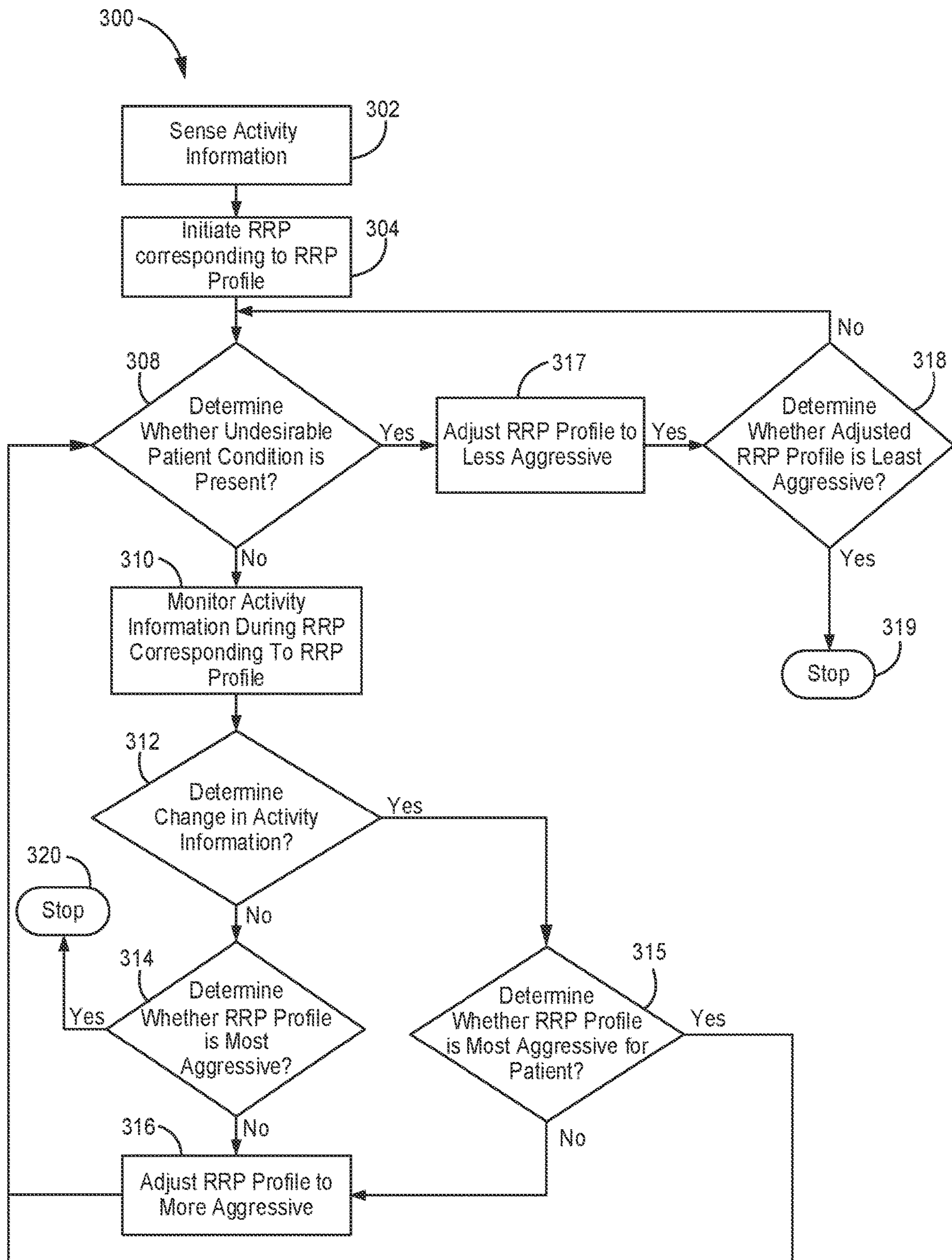


FIG. 7

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RATE RESPONSIVE PACING

This disclosure generally relates to cardiac pacing methods and systems, and more particularly, to methods and systems for delivering rate responsive pacing with an implantable medical device.

Heart failure (HF) is a complex disease that is broadly defined by an inability of the heart to pump sufficiently to cope with its venous return and/or to deliver sufficient output to meet the metabolic demands of the body. Heart failure is an increasingly common, life-threatening cardiovascular disorder, characterized by marked disability, frequent hospitalization, and high mortality. HF is increasingly prevalent in older individuals (up to 10% of the population) and it has become the most common cause for hospitalization in people >65 yrs. HF is a leading cause or contributor to hospitalization, and therefore, is emerging as a substantial contributor to healthcare spending.

Congestive heart failure symptoms (e.g., indicative of congestive heart failure) may include reduced cardiac output leading to easy fatigue and organ dysfunction (e.g. renal), and to symptoms related to congestion either in the lungs (causing breathlessness) or peripherally (leading to swelling of the lower limbs and abdomen).

A possible correlation has been identified between sedentary lifestyle and risk of ventricular arrhythmias based on a comparison of occurrences of ventricular arrhythmias in healthy active vs. sedentary patients, and patients with previous myocardial infarction. One result of a sedentary lifestyle is that the size of the chambers of the heart may decrease, which often occurs as a result of increased muscle thickness. The reduced chamber size leads to decreased stroke volume (SV, amount of blood ejected with each heart beat), even though the fraction of blood (ejection fraction) ejected with each beat is preserved. Reduced stroke volume per beat leads to reduced cardiac output (CO, $CO=SV*\text{heart rate (HR)}$). Cardiac output is typically measured in liters of blood pumped per minute by heart. A reduced cardiac output may mean that the body's metabolic demand, especially during periods of ambulation or exercise is not met. This leads to heart failure symptoms such as dyspnea (shortness of breath) with activities of daily living (ADL). This type of heart failure in which ejection fraction (EF) is preserved is referred to as heart failure with preserved ejection fraction (HFpEF). From the relationship between $CO=SV*HR$, it can be seen that one way to increase cardiac output and meet the body's demand during periods of ambulation, activities of daily living, and exercise is to increase the HR appropriately.

In congestive heart failure patients with HFpEF the amount of blood pumped from the heart's left ventricle with each beat (ejection fraction) is greater than 50%. HFpEF is also commonly known as diastolic heart failure or diastolic dysfunction, as the deficit in function frequently relates to changes occurring during diastole and filling of the ventricles. Approximately half of people with heart failure have HFpEF, while the remainder display a reduction in ejection fraction, or heart failure with reduced ejection fraction (HFrEF).

The prevalence of HFpEF continues to increase, likely because of the increasing prevalence of common risk factors, including older age, hypertension, metabolic syndrome, renal dysfunction and obesity. HFpEF is characterized by abnormal diastolic function, which manifests as an increase in the stiffness of the heart's left ventricle, a decrease in left ventricular relaxation when filling with blood before the next beat, and decreased chamber volume, which often

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occurs as a result of increased muscle thickness. There is an increased risk for atrial fibrillation and pulmonary hypertension for patient's experiencing HFpEF.

Chronotropic incompetence (CI) is common among HFpEF patients and is characterized by decreased heart rate response during activities of daily living or other activities requiring increase in cardiac output (e.g., exercise). HFpEF patients with CI often cannot elevate their sinus/atrial rate. Maximum exercise and peak heart rate achieved during exercise are both decreased in a patient with CI.

Cardiac pacing is delivered according to a pacing rate. The pacing rate may be described as the rate at which the heart is paced thereby increasing or decreasing the patient's heart rate. The pacing rate may be defined in terms of beats per minute. In some examples, the pacing rate may be defined in terms of R-R interval that is the time between successive heartbeats. Rate responsive pacing can adapt the pacing rate to changes in the patient's physical activity. Rate responsive pacing can be useful to allow the heart rate to increase with increased metabolic demand, such as during activities of daily living and exercise, for example.

SUMMARY

The techniques of this disclosure generally relate to a method and device for delivering a rate responsive pacing therapy to a patient's heart over a period of time.

Some aspects, in accordance with principles of the present disclosure, relate to a method including monitoring activity information related to an activity level of a patient, delivering rate responsive pacing (RRP) to the patient at a pacing rate corresponding to a RRP profile, wherein the RRP profile generates the pacing rate based on the activity information, and adjusting the RRP profile based on the monitored activity information.

Other aspects, in accordance with principles of the present disclosure, relate to an implantable medical device including a sensing apparatus, a control apparatus, and an electrode apparatus. The sensing apparatus may include one or more sensors to sense activity information of a patient. The control apparatus includes processing circuitry to select a rate responsive pacing (RRP) profile based on the sensed activity information received from the sensing apparatus. The electrode apparatus includes a plurality of pacing electrodes, the electrode apparatus operably coupled to the control apparatus. The electrode apparatus delivers rate responsive pacing (RRP) to the patient at a pacing rate corresponding to the RRP profile. The RRP profile is adjustable based on the sensed activity information.

Other aspects, in accordance with principles of the present disclosure, relate to a rate responsive pacing system including a sensing apparatus, a control apparatus, and an implantable medical device. The sensing apparatus may include one or more sensors to sense activity information of a patient. The control apparatus includes processing circuitry. The control apparatus is operably coupled to the sensing apparatus and is configured to monitor sensed activity information of the patient, determine a first activity information of a patient related to a first activity level of the patient, and determine a second activity information related to a second activity level of the patient, compare the first activity information to the second activity information, and determine a rate responsive pacing (RRP) profile based on the compared activity information. The implantable medical device includes pacing electrodes and may be operably coupled to

the control apparatus. The electrodes deliver rate responsive pacing (RRP) to the patient at a pacing rate corresponding to the determined RRP profile.

The details of one or more aspects of the disclosure are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the techniques described in this disclosure will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF DRAWINGS

FIG. 1 is a diagram of an illustrative system including an illustrative implantable medical device (IMD).

FIG. 2A is a diagram of the illustrative IMD of FIG. 1.

FIG. 2B is a diagram of an enlarged view of a distal end of the electrical lead disposed in the left ventricle of FIG. 2A

FIG. 3A is a block diagram of an illustrative IMD, e.g., of the systems of FIGS. 1-2B.

FIG. 3B is another block diagram of an illustrative IMD (e.g., an implantable pulse generator) circuitry and associated leads employed in the systems of FIGS. 1-2B.

FIG. 4 is an illustrative block diagram of a therapy system for delivering cardiac therapy in accordance with aspects of the present disclosure.

FIG. 5 is a graphical representation of some example RRP profiles useful in a cardiac therapy system in accordance with aspects of the present disclosure.

FIG. 6 illustrates an example method of delivering RRP therapy in accordance with aspects of the present disclosure.

FIG. 7 illustrates another example method of delivering RRP therapy in accordance with aspects of the present disclosure.

DETAILED DESCRIPTION

It should be understood that various aspects disclosed herein may be combined in different combinations than the combinations specifically presented in the description and accompanying drawings. It should also be understood that, depending on the example, certain acts or events of any of the processes or methods described herein may be performed in a different sequence, may be added, merged, or left out altogether (e.g., all described acts or events may not be necessary to carry out the techniques). In addition, while certain aspects of this disclosure are described as being performed by a single module or apparatus for purposes of clarity, it should be understood that the techniques of this disclosure may be performed by a combination of units or apparatuses associated with, for example, an implantable medical device.

Illustrative cardiac therapy systems and devices may be further described herein with reference to FIGS. 1-3B that may utilize the illustrative systems, methods, and processes described herein with respect to FIGS. 4-7.

FIG. 1 is a conceptual diagram illustrating an illustrative therapy system 10 that may be used to deliver pacing therapy, such as cardiac rate responsive pacing (RRP) to a patient 14. Patient 14 may, but not necessarily, be a human. The therapy system 10 may include an implantable medical device 16 (IMD), which may be coupled to leads 18, 20, 22. The IMD 16 may be, e.g., an implantable pacemaker, cardioverter, and/or defibrillator, that delivers, or provides, electrical signals (e.g., paces, etc.) to and/or senses electrical signals from the heart 12 of the patient 14 via electrodes coupled to one or more of the leads 18, 20, 22.

The leads 18, 20, 22 extend into the heart 12 of the patient 14 to sense electrical activity of the heart 12 and/or to deliver

electrical stimulation to the heart 12. In the example shown in FIG. 1, the right ventricular (RV) lead 18 extends through one or more veins (not shown), the superior vena cava (not shown), and the right atrium 26, and into the right ventricle 28. The right atrial (RA) lead 22 extends through one or more veins and the vena cava, and into the right atrium 26 of the heart 12.

The IMD 16 may sense, among other things, electrical signals attendant to the depolarization and repolarization of the heart 12 via electrodes coupled to at least one of the leads 18, 20, 22. In some examples, the IMD 16 provides pacing therapy (e.g., pacing pulses) to the heart 12 based on the electrical signals sensed within the heart 12. The IMD 16 may be operable to adjust one or more parameters associated with the pacing therapy such as, e.g., pacing rate, R-R interval, A-V delay and other various timings, pulse width, amplitude, voltage, burst length, etc. Further, the IMD 16 may be operable to use various electrode configurations to deliver pacing therapy, which may be unipolar, bipolar, quadripolar, or further multipolar. Hence, a multipolar lead system may provide, or offer, multiple electrical vectors to pace from. A pacing vector may include at least one cathode, which may be at least one electrode located on at least one lead, and at least one anode, which may be at least one electrode located on at least one lead (e.g., the same lead, or a different lead) and/or on the casing, or can, of the IMD, or electrode apparatus. While improvement in cardiac function as a result of the pacing therapy may primarily depend on the cathode, the electrical parameters like impedance, pacing threshold voltage, current drain, longevity, etc. may be more dependent on the pacing vector, which includes both the cathode and the anode. The IMD 16 may also provide defibrillation therapy and/or cardioversion therapy via electrodes located on at least one of the leads 18, 20, 22. Further, the IMD 16 may detect arrhythmia of the heart 12, such as fibrillation of the ventricles 28, 32, and deliver defibrillation therapy to the heart 12 in the form of electrical pulses. In some examples, IMD 16 may be programmed to deliver a progression of therapies, e.g., pulses with increasing energy levels, until a fibrillation of heart 12 is stopped.

FIGS. 2A-2B are conceptual diagrams illustrating the IMD 16 and the leads 18, 20, 22 of therapy system 10 of FIG. 1 in more detail. The leads 18, 20, 22 may be electrically coupled to a therapy delivery module (e.g., for delivery of pacing therapy), a sensing module (e.g., for sensing one or more signals from one or more electrodes), and/or any other modules of the IMD 16 via a connector block 34. In some examples, the proximal ends of the leads 18, 20, 22 may include electrical contacts that electrically couple to respective electrical contacts within the connector block 34 of the IMD 16. In addition, in some examples, the leads 18, 20, 22 may be mechanically coupled to the connector block 34 with the aid of set screws, connection pins, or another suitable mechanical coupling mechanism.

Each of the leads 18, 20, 22 includes an elongated insulative lead body, which may carry a number of conductors (e.g., concentric coiled conductors, straight conductors, etc.) separated from one another by insulation (e.g., tubular insulative sheaths). In the illustrated example, bipolar electrodes 40, 42 are located proximate to a distal end of the lead 18. In addition, bipolar electrodes 44, 45, 46, 47 are located proximate to a distal end of the lead 20 and bipolar electrodes 48, 50 are located proximate to a distal end of the lead 22.

The electrodes 40, 44, 45, 46, 47, 48 may take the form of ring electrodes, and the electrodes 42, 50 may take the form of extendable helix tip electrodes mounted retractably

within the insulative electrode heads **52, 54, 56**, respectively. Each of the electrodes **40, 42, 44, 45, 46, 47, 48, 50** may be electrically coupled to a respective one of the conductors (e.g., coiled and/or straight) within the lead body of its associated lead **18, 20, 22**, and thereby coupled to a respective one of the electrical contacts on the proximal end of the leads **18, 20, 22**.

The electrodes **40, 42, 44, 45, 46, 47, 48, 50** may further be used to sense electrical signals (e.g., morphological waveforms within electrograms (EGM)) attendant to the depolarization and repolarization of the heart **12**. The electrical signals are conducted to the IMD **16** via the respective leads **18, 20, 22**. In some examples, the IMD **16** may also deliver pacing pulses via the electrodes **40, 42, 44, 45, 46, 47, 48, 50** to cause depolarization of cardiac tissue of the patient's heart **12**. In some examples, as illustrated in FIG. 2A, the IMD **16** includes one or more housing electrodes, such as housing electrode **58**, which may be formed integrally with an outer surface of a housing **60** (e.g., hermetically-sealed housing) of the IMD **16** or otherwise coupled to the housing **60**. Any of the electrodes **40, 42, 44, 45, 46, 47, 48, 50** may be used for unipolar sensing or pacing in combination with the housing electrode **58**. It is generally understood by those skilled in the art that other electrodes can also be selected to define, or be used for, pacing and sensing vectors. Further, any of electrodes **40, 42, 44, 45, 46, 47, 48, 50, 58**, when not being used to deliver pacing therapy, may be used to sense electrical activity during pacing therapy.

As described in further detail with reference to FIG. 2A, the housing **60** may enclose a therapy delivery module that may include a stimulation generator for generating cardiac pacing pulses and defibrillation or cardioversion shocks, as well as a sensing module for monitoring the electrical signals of the patient's heart (e.g., the patient's heart rhythm). The leads **18, 20, 22** may also include elongated electrodes **62, 64, 66**, respectively, which may take the form of a coil. The IMD **16** may deliver defibrillation shocks to the heart **12** via any combination of the elongated electrodes **62, 64, 66** and the housing electrode **58**. The electrodes **58, 62, 64, 66** may also be used to deliver cardioversion pulses to the heart **12**. Further, the electrodes **62, 64, 66** may be fabricated from any suitable electrically conductive material, such as, but not limited to, platinum, platinum alloy, and/or other materials known to be usable in implantable defibrillation electrodes. Since electrodes **62, 64, 66** are not generally configured to deliver pacing therapy, any of electrodes **62, 64, 66** may be used to sense electrical activity and may be used in combination with any of electrodes **40, 42, 44, 45, 46, 47, 48, 50, 58**. In at least one embodiment, the RV elongated electrode **62** may be used to sense electrical activity of a patient's heart during the delivery of pacing therapy (e.g., in combination with the housing electrode **58**, or defibrillation electrode-to-housing electrode vector).

The configuration of the illustrative therapy system **10** illustrated in FIGS. 1-3B is merely one example. In other examples, the therapy system may include epicardial leads and/or patch electrodes instead of or in addition to the transvenous leads **18, 20, 22** illustrated in FIG. 1. Additionally, in other examples, the therapy system **10** may be implanted in/around the cardiac space without transvenous leads (e.g., leadless/wireless pacing systems) or with leads implanted (e.g., implanted transvenously or using approaches) into the left chambers of the heart (in addition to or replacing the transvenous leads placed into the right chambers of the heart as illustrated in FIG. 1). In one example, the left ventricular (LV) coronary sinus lead **20**

extends through one or more veins, the vena cava, the right atrium **26**, and into the coronary sinus **30** to a region adjacent to the free wall of the left ventricle **32** of the heart **12**. Further, in one or more embodiments, the IMD **16** need not be implanted within the patient **14**. For example, the IMD **16** may deliver various cardiac therapies to the heart **12** via percutaneous leads that extend through the skin of the patient **14** to a variety of positions within or outside of the heart **12**. In one or more embodiments, the system **10** may utilize wireless pacing (e.g., using energy transmission to the intracardiac pacing component(s) via ultrasound, inductive coupling, RF, etc.) and sensing cardiac activation using electrodes on the can/housing and/or on subcutaneous leads.

In other examples of therapy systems that provide electrical stimulation therapy to the heart **12**, such therapy systems may include any suitable number of leads coupled to the IMD **16**, and each of the leads may extend to any location within or proximate to the heart **12**. For example, other examples of therapy systems may include three transvenous leads located as illustrated in FIGS. 1-3B. Still further, other therapy systems may include a single lead that extends from the IMD **16** into the right atrium **26** or two leads that extend into a respective one of the right atrium **26** and the left atrium. In one example, the IMD **16**, as a cardiac resynchronization therapy (CRT) device with a left ventricular (LV) lead may be useful for a HFpEF patient if there is a complete AV node block, as a LV lead can be more beneficial than a RV lead in such patients. In some examples, it can be desirable to deliver rate responsive pacing to the atrium for a HFpEF patient with CI with an atrial lead (i.e. single chamber atrial system such as AAI) and atrial and ventricular lead system (i.e. dual chamber system such as DDD and VDD).

FIG. 3A is a functional block diagram of one illustrative configuration of the IMD **16**. As shown, the IMD **16** may include a control module **81**, a therapy delivery module **84** (e.g., which may include a stimulation generator), a sensing module **86**, and a power source **90**. The control module, or apparatus, **81** may include a processor **80**, memory **82**, and a telemetry module, or apparatus, **88**. The memory **82** may include computer-readable instructions that, when executed, e.g., by the processor **80**, cause the IMD **16** and/or the control module **81** to perform various functions attributed to the IMD **16** and/or the control module **81** described herein. Further, the memory **82** may include any volatile, non-volatile, magnetic, optical, and/or electrical media, such as a random-access memory (RAM), read-only memory (ROM), non-volatile RAM (NVRAM), electrically-erasable programmable ROM (EEPROM), flash memory, and/or any other digital media.

The processor **80** of the control module **81** may include any one or more of a microprocessor, a controller, a digital signal processor (DSP), an application specific integrated circuit (ASIC), a field-programmable gate array (FPGA), and/or equivalent discrete or integrated logic circuitry. In some examples, the processor **80** may include multiple components, such as any combination of one or more microprocessors, one or more controllers, one or more DSPs, one or more ASICs, and/or one or more FPGAs, as well as other discrete or integrated logic circuitry. The functions attributed to the processor **80** herein may be embodied as software, firmware, hardware, or any combination thereof.

The control module **81** may control the therapy delivery module, or apparatus, **84** to deliver therapy (e.g., electrical stimulation therapy such as pacing) to the heart **12** according to a selected one or more therapy programs, which may be

stored in the memory **82**. More, specifically, the control module **81** (e.g., the processor **80**) may control various parameters of the electrical stimulus delivered by the therapy delivery module **84** such as, e.g., A-V delays, pacing pulses with the amplitudes, pulse widths, frequency, or electrode polarities, etc., which may be specified by one or more selected therapy programs (e.g., A-V delay adjustment programs, pacing therapy programs, pacing recovery programs, capture management programs, etc.). As shown, the therapy delivery module **84** is electrically coupled to electrodes **40, 42, 44, 45, 46, 47, 48, 50, 58, 62, 64, 66**, e.g., via conductors of the respective lead **18, 20, 22**, or, in the case of housing electrode **58**, via an electrical conductor disposed within housing **60** of IMD **16**. Therapy delivery module **84** may be configured to generate and deliver electrical stimulation therapy such as pacing therapy to the heart **12** using one or more of the electrodes **40, 42, 44, 45, 46, 47, 48, 50, 58, 62, 64, 66**.

For example, the therapy delivery module **84** may deliver pacing stimulus (e.g., pacing pulses) via ring electrodes **40, 44, 45, 46, 47, 48** coupled to leads **18, 20, 22** and/or helical tip electrodes **42, 50** of leads **18, 22**. Further, for example, therapy delivery module **84** may deliver defibrillation shocks to heart **12** via at least two of electrodes **58, 62, 64, 66**. In some examples, therapy delivery module **84** may be configured to deliver pacing, cardioversion, or defibrillation stimulation in the form of electrical pulses. In other examples, therapy delivery module **84** may be configured to deliver one or more of these types of stimulation in the form of other signals, such as sine waves, square waves, and/or other substantially continuous time signals.

The IMD **16** may further include a switch module, or apparatus, **85** and the control module **81** (e.g., the processor **80**) may use the switch module **85** to select, e.g., via a data/address bus, which of the available electrodes are used to deliver therapy such as pacing pulses for pacing therapy, or which of the available electrodes are used for sensing. The switch module **85** may include a switch array, switch matrix, multiplexer, or any other type of switching device suitable to selectively couple the sensing module, or apparatus, **86** and/or the therapy delivery module **84** to one or more selected electrodes. More specifically, the therapy delivery module **84** may include a plurality of pacing output circuits. Each pacing output circuit of the plurality of pacing output circuits may be selectively coupled, e.g., using the switch module **85**, to one or more of the electrodes **40, 42, 44, 45, 46, 47, 48, 50, 58, 62, 64, 66** (e.g., a pair of electrodes for delivery of therapy to a bipolar or multipolar pacing vector). In other words, each electrode can be selectively coupled to one of the pacing output circuits of the therapy delivery module using the switching module **85**.

The sensing module **86** is coupled (e.g., electrically coupled) to sensing apparatus, which may include, among additional sensing apparatus, the electrodes **40, 42, 44, 45, 46, 47, 48, 50, 58, 62, 64, 66** to monitor electrical activity of the heart **12**, e.g., electrocardiogram (ECG)/electrogram (EGM) signals, etc. The ECG/EGM signals may be used to measure or monitor activation times (e.g., ventricular activations times, etc.), heart rate (HR), heart rate variability (HRV), heart rate turbulence (HRT), deceleration/acceleration capacity, deceleration sequence incidence, T-wave alternans (TWA), P-wave to P-wave intervals (also referred to as the P-P intervals or A-A intervals), R-wave to R-wave intervals (also referred to as the R-R intervals or V-V intervals), P-wave to QRS complex intervals (also referred to as the P-R intervals, A-V intervals, or P-Q intervals), QRS-complex morphology, ST segment (i.e., the segment

that connects the QRS complex and the T-wave), T-wave changes, QT intervals, electrical vectors, etc.

The switch module **85** may also be used with the sensing module **86** to select which of the available electrodes are used, or enabled, to, e.g., sense electrical activity of the patient's heart (e.g., one or more electrical vectors of the patient's heart using any combination of the electrodes **40, 42, 44, 45, 46, 47, 48, 50, 58, 62, 64, 66**). Likewise, the switch module **85** may also be used with the sensing module **86** to select which of the available electrodes are not to be used (e.g., disabled) to, e.g., sense electrical activity of the patient's heart (e.g., one or more electrical vectors of the patient's heart using any combination of the electrodes **40, 42, 44, 45, 46, 47, 48, 50, 58, 62, 64, 66**), etc. In some examples, the control module **81** may select the electrodes that function as sensing electrodes via the switch module within the sensing module **86**, e.g., by providing signals via a data/address bus.

In some examples, sensing module **86** includes a channel that includes an amplifier with a relatively wider pass band than the R-wave or P-wave amplifiers. Signals from the selected sensing electrodes may be provided to a multiplexer, and thereafter converted to multi-bit digital signals by an analog-to-digital converter for storage in memory **82**, e.g., as an electrogram (EGM). In some examples, the storage of such EGMs in memory **82** may be under the control of a direct memory access circuit.

In some examples, the control module **81** may operate as an interrupt-driven device and may be responsive to interrupts from pacer timing and control module, where the interrupts may correspond to the occurrences of sensed P-waves and R-waves and the generation of cardiac pacing pulses. Any necessary mathematical calculations may be performed by the processor **80** and any updating of the values or intervals controlled by the pacer timing and control module may take place following such interrupts. A portion of memory **82** may be configured as a plurality of recirculating buffers, capable of holding one or more series of measured intervals, which may be analyzed by, e.g., the processor **80** in response to the occurrence of a pace or sense interrupt to determine whether the patient's heart **12** is presently exhibiting atrial or ventricular tachyarrhythmia.

The telemetry module **88** of the control module **81** may include any suitable hardware, firmware, software, or any combination thereof for communicating with another device, such as a programmer. For example, under the control of the processor **80**, the telemetry module **88** may receive downlink telemetry from and send uplink telemetry to a programmer with the aid of an antenna, which may be internal and/or external. The processor **80** may provide the data to be uplinked to a programmer and the control signals for the telemetry circuit within the telemetry module **88**, e.g., via an address/data bus. In some examples, the telemetry module **88** may provide received data to the processor **80** via a multiplexer.

The various components of the IMD **16** are further coupled to a power source **90**, which may include a rechargeable or non-rechargeable battery. A non-rechargeable battery may be selected to last for several years, while a rechargeable battery may be inductively charged from an external device, e.g., on a daily or weekly basis.

FIG. **3B** is another embodiment of a functional block diagram for IMD **16** that depicts bipolar RA lead **22**, bipolar RV lead **18** without the LA CS pace/sense electrodes and coupled with an implantable pulse generator (IPG) circuit **31** having programmable modes and parameters of a bi-ventricular DDD/R type known in the pacing art. In turn, the

sensor signal processing circuit **91** indirectly couples to the timing circuit **43** and via data and control bus to microcomputer circuitry **33**. The IPG circuit **31** is illustrated in a functional block diagram divided generally into a microcomputer circuit **33** and a pacing circuit **21**. The pacing circuit **21** includes the digital controller/timer circuit **43**, the output amplifiers circuit **51**, the sense amplifiers circuit **55**, the RF telemetry transceiver **41**, the activity sensor circuit **35** as well as a number of other circuits and components described below.

Crystal oscillator circuit **89** provides the basic timing clock for the pacing circuit **21** while battery **29** provides power. Power-on-reset circuit **87** responds to initial connection of the circuit to the battery for defining an initial operating condition and similarly, resets the operative state of the device in response to detection of a low battery condition. Reference mode circuit **37** generates stable voltage reference and currents for the analog circuits within the pacing circuit **21**. Analog-to-digital converter (ADC) and multiplexer circuit **39** digitize analog signals and voltage to provide, e.g., real time telemetry of cardiac signals from sense amplifiers **55** for uplink transmission via RF transmitter and receiver circuit **41**. Voltage reference and bias circuit **37**, ADC and multiplexer **39**, power-on-reset circuit **87**, and crystal oscillator circuit **89** may correspond to any of those used in illustrative implantable cardiac pacemakers.

If the IPG is programmed to a rate responsive mode, the signals output by one or more physiologic sensors are employed as a rate control parameter (RCP) to derive a physiologic escape interval. For example, the escape interval is adjusted proportionally to the patient's activity level developed in the patient activity sensor (PAS) circuit **35** in the depicted, illustrative IPG circuit **31**. The patient activity sensor **27** is coupled to the IPG housing and may take the form of a piezoelectric crystal transducer. The output signal of the patient activity sensor **27** may be processed and used as an RCP. Sensor **27** generates electrical signals in response to sensed physical activity that are processed by activity circuit **35** and provided to digital controller/timer circuit **43**. Similarly, the illustrative systems, apparatus, and methods described herein may be practiced in conjunction with alternate types of sensors such as oxygenation sensors, pressure sensors, pH sensors, temperature sensors, respiration sensors, perfusion sensors, heart sound sensors, and heart rate sensors, for use in providing rate responsive pacing capabilities. For example, impedance can be measured using a ring electrode on the lead (e.g., RA or RV lead) and temperature can be measured by a sensor at the distal end of the lead. Alternately, QT time may be used as a rate indicating parameter, in which case no extra sensor is required. Similarly, the illustrative embodiments described herein may also be practiced in non-rate responsive pacemakers.

Data transmission to and from the external programmer is accomplished by way of the telemetry antenna **57** and an associated RF transceiver **41**, which serves both to demodulate received downlink telemetry and to transmit uplink telemetry. Uplink telemetry capabilities may include the ability to transmit stored digital information, e.g., activity information, RRP profiles, operating modes and parameters, EGM histograms, and other events, as well as real time EGMs of atrial and/or ventricular electrical activity and marker channel pulses indicating the occurrence of sensed and paced depolarizations in the atrium and ventricle.

Microcomputer **33** contains a microprocessor **80** and associated system clock and on-processor RAM and ROM chips **82A** and **82B**, respectively. In addition, microcom-

puter circuit **33** includes a separate RAM/ROM chip **82C** to provide additional memory capacity. Microprocessor **80** normally operates in a reduced power consumption mode and is interrupt driven. Microprocessor **80** is awakened in response to defined interrupt events, which may include A-TRIG, RV-TRIG, LV-TRIG signals generated by timers in digital timer/controller circuit **43** and A-EVENT, RV-EVENT, and LV-EVENT signals generated by sense amplifiers circuit **55**, among others. The specific values of the intervals and delays timed out by digital controller/timer circuit **43** are controlled by the microcomputer circuit **33** by way of data and control bus from programmed-in parameter values and operating modes. In addition, if programmed to operate as a rate responsive pacemaker, a timed interrupt, e.g., every cycle or every two seconds, may be provided in order to allow the microprocessor to analyze the activity sensor data and update the basic pacing rate as well as A-A, V-A, as applicable. In addition, the microprocessor **80** may also serve to define variable, operative A-V delay intervals, and the energy delivered to each ventricle and/or atrium.

In one embodiment, microprocessor **80** is a custom microprocessor adapted to fetch and execute instructions stored in RAM/ROM unit **82** in a conventional manner. It is contemplated, however, that other implementations may be suitable to practice the present disclosure. For example, an off-the-shelf, commercially available microprocessor or microcontroller, or custom application-specific, hardwired logic, or state-machine type circuit may perform the functions of microprocessor **80**.

Digital controller/timer circuit **43** operates under the general control of the microcomputer **33** to control timing and other functions within the pacing circuit **21** and includes a set of timing and associated logic circuits of which certain ones pertinent to the present disclosure are depicted. The depicted timing circuits include URI/LRI timers **83A**, V-V delay timer **83B**, intrinsic interval timers **83C** for timing elapsed V-EVENT to V-EVENT intervals or V-EVENT to A-EVENT intervals, escape interval timers **83D** for timing A-A, and/or V-A pacing escape intervals, an A-V delay interval timer **83E** for timing the A-LVp delay (or A-RVp delay) from a preceding A-EVENT or A-TRIG, a post-ventricular timer **83F** for timing post-ventricular time periods, and a date/time clock **83G**.

The A-V delay interval timer **83E** is loaded with an appropriate delay interval for one ventricular chamber (e.g., either an A-RVp delay or an A-LVp) to time-out starting from a preceding A-PACE or A-EVENT. The interval timer **83E** triggers pacing stimulus delivery and can be based on one or more prior cardiac cycles (or from a data set empirically derived for a given patient).

The post-event timer **83F** times out the post-ventricular time period following an RV-EVENT or LV-EVENT or a RV-TRIG or LV-TRIG and post-atrial time periods following an A-EVENT or A-TRIG. The durations of the post-event time periods may also be selected as programmable parameters stored in the microcomputer **33**. The post-ventricular time periods include a post-ventricular atrial blanking period (PVARP), a post-atrial ventricular blanking period (PAVBP), a ventricular blanking period (VBP), and a ventricular refractory period (VRP) although other periods can be suitably defined depending, at least in part, on the operative circuitry employed in the pacing engine. The post-atrial time periods include an atrial refractory period (ARP) during which an A-EVENT is ignored for the purpose of resetting any A-V delay, and an atrial blanking period (ABP) during which atrial sensing is disabled. It should be noted that the starting of the post-atrial time periods and the

A-V delays can be commenced substantially simultaneously with the start or end of each A-EVENT or A-TRIG or, in the latter case, upon the end of the A-PACE which may follow the A-TRIG. Similarly, the starting of the post-ventricular time periods and the V-A escape interval can be commenced substantially simultaneously with the start or end of the V-EVENT or V-TRIG or, in the latter case, upon the end of the V-PACE which may follow the V-TRIG. The microprocessor **80** also optionally calculates A-V delays, post-ventricular time periods, and post-atrial time periods that vary with the sensor-based escape interval established in response to the RCP(s) and/or with the intrinsic atrial and/or ventricular rate.

The output amplifiers circuit **51** contains a RA pace pulse generator (and a LA pace pulse generator if LA pacing is provided), a RV pace pulse generator, a LV pace pulse generator, and/or any other pulse generator configured to provide atrial and ventricular pacing. In order to trigger generation of an RV-PACE or LV-PACE pulse, digital controller/timer circuit **43**.

The output amplifiers circuit **51** includes switching circuits for coupling selected pace electrode pairs from among the lead conductors and the IND-CAN electrode **20** to the RA pace pulse generator (and LA pace pulse generator if provided), RV pace pulse generator and LV pace pulse generator. Pace/sense electrode pair selection and control circuit **53** selects lead conductors and associated pace electrode pairs to be coupled with the atrial and ventricular output amplifiers within output amplifiers circuit **51** for accomplishing RA, LA, RV and LV pacing.

The sense amplifiers circuit **55** contains sense amplifiers for atrial and ventricular pacing and sensing. High impedance P-wave and R-wave sense amplifiers may be used to amplify a voltage difference signal that is generated across the sense electrode pairs by the passage of cardiac depolarization wavefronts. The high impedance sense amplifiers use high gain to amplify the low amplitude signals and rely on pass band filters, time domain filtering and amplitude threshold comparison to discriminate a P-wave or R-wave from background electrical noise. Digital controller/timer circuit **43** controls sensitivity settings of the atrial and ventricular sense amplifiers **55**.

The sense amplifiers may be uncoupled from the sense electrodes during the blanking periods before, during, and after delivery of a pace pulse to any of the pace electrodes of the pacing system to avoid saturation of the sense amplifiers. The sense amplifiers circuit **55** includes blanking circuits for uncoupling the selected pairs of the lead conductors and the IND-CAN electrode **20** from the inputs of the RA sense amplifier (and LA sense amplifier if provided), RV sense amplifier and LV sense amplifier during the ABP, PVABP and VBP. The sense amplifiers circuit **55** also includes switching circuits for coupling selected sense electrode lead conductors and the IND-CAN electrode **20** to the RA sense amplifier (and LA sense amplifier if provided), RV sense amplifier and LV sense amplifier. Again, sense electrode selection and control circuit **53** selects conductors and associated sense electrode pairs to be coupled with the atrial and ventricular sense amplifiers within the output amplifiers circuit **51** and sense amplifiers circuit **55** for accomplishing RA, LA, RV, and LV sensing along desired unipolar and bipolar sensing vectors.

Right atrial depolarizations or P-waves in the RA-SENSE signal that are sensed by the RA sense amplifier result in a RA-EVENT signal that is communicated to the digital controller/timer circuit **43**. Similarly, left atrial depolarizations or P-waves in the LA-SENSE signal that are sensed by

the LA sense amplifier, if provided, result in a LA-EVENT signal that is communicated to the digital controller/timer circuit **43**. Ventricular depolarizations or R-waves in the RV-SENSE signal are sensed by a ventricular sense amplifier result in an RV-EVENT signal that is communicated to the digital controller/timer circuit **43**. Similarly, ventricular depolarizations or R-waves in the LV-SENSE signal are sensed by a ventricular sense amplifier result in an LV-EVENT signal that is communicated to the digital controller/timer circuit **43**. The RV-EVENT, LV-EVENT, and RA-EVENT, LA-SENSE signals may be refractory or non-refractory, and can inadvertently be triggered by electrical noise signals or aberrantly conducted depolarization waves rather than true R-waves or P-waves.

The techniques described in this disclosure, including those attributed to the IMD **16** and/or various constituent components, may be implemented, at least in part, in hardware, software, firmware, or any combination thereof. For example, various aspects of the techniques may be implemented within one or more processors, including one or more microprocessors, DSPs, ASICs, FPGAs, or any other equivalent integrated or discrete logic circuitry, as well as any combinations of such components, embodied in programmers, such as physician or patient programmers, stimulators, image processing devices, or other devices. The term "module," "processor," or "processing circuitry" may generally refer to any of the foregoing logic circuitry, alone or in combination with other logic circuitry, or any other equivalent circuitry.

Such hardware, software, and/or firmware may be implemented within the same device or within separate devices to support the various operations and functions described in this disclosure. In addition, any of the described units, modules, or components may be implemented together or separately as discrete but interoperable logic devices. Depiction of different features as modules or units is intended to highlight different functional aspects and does not necessarily imply that such modules or units must be realized by separate hardware or software components. Rather, functionality associated with one or more modules or units may be performed by separate hardware or software components, or integrated within common or separate hardware or software components.

When implemented in software, the functionality ascribed to the systems, devices and techniques described in this disclosure may be embodied as instructions on a computer-readable medium such as RAM, ROM, NVRAM, EEPROM, FLASH memory, magnetic data storage media, optical data storage media, or the like. The instructions may be executed by one or more processors to support one or more aspects of the functionality described in this disclosure.

The illustrative systems, devices, and rate responsive pacing methods may be used to provide evaluation of a patient's cardiac health and/or evaluation and configuration of cardiac therapy being delivered to the patient. For example, the illustrative systems, devices, and rate responsive pacing methods may be used to determine and adjust a rate responsive pacing profile, as described further herein, based on activity information monitored over time.

FIG. **4** is an illustrative block diagram of a therapy system **100** for delivering cardiac therapy in accordance with aspects of the present disclosure. The therapy system **100** can be a rate responsive pacing system for delivering RRP to a patient. The therapy system **100** includes a sensing apparatus **186**, a control apparatus **181**, and an implantable medical device **160** (IMD). The sensing apparatus **186**, the

control apparatus **181**, and the implantable medical device **160** are similar to, and include features akin to, those discussed above with respect to the sensing apparatus **86**, the control apparatus **81**, and the implantable medical device **60**. For example, the sensing apparatus **186** may include one or more sensors (e.g., configured to sense a patient's activity to provide activity info and activity levels), the control apparatus **181** includes processing circuitry, and the implantable medical device **160** (or electrode apparatus) includes a plurality of pacing electrodes, as similarly discussed above with respect to FIG. 3B. The control apparatus **181** is operably coupled to the sensing apparatus **186** and the implantable medical device **160** is operably coupled to the control apparatus **181** as indicated by lines **101** and **103**, respectively. In one example, the sensing apparatus **186** can be operably coupled to the implantable medical device, as indicated with the dashed line **105**.

It is to be understood that the control apparatus **181** and the sensing apparatus **186**, and similarly, the control apparatus **181** and the implantable medical device **160**, may be operatively coupled to each other in a plurality of different ways so as to perform, or execute, the functionality described herein. For example, the control apparatus **181** may be wirelessly operably coupled to the sensing apparatus **186** as depicted by the line **101** extending therebetween. In one example, one or both of the sensing apparatus **186** and the control apparatus **181** can be included within the implantable medical device **160**. In one example, the control apparatus **181** is included in a remote computing device (not shown) that may be operably coupled (e.g., wirelessly) to the sensing apparatus **186** and the implantable medical device **160**.

The sensing apparatus **186** is employed to sense and collect activity information related to, or based on, the patient's physiological response of the patient's body indicative of movement, such as exercise. The sensing apparatus **186** includes a sensor to sense activity information of a patient. For example, the sensing apparatus **186** may be configured to sense an increase or decrease in the patient's physical activity. The sensing apparatus **186** can include one or more than one sensor or type of sensors. The sensing apparatus **186** can sense, for example, at least one of patient movement information, pulse wave velocity signals, electrocardiogram signals, intracardiac electrogram signals, blood pressure measurement, transthoracic impedance, subcutaneous impedance, temperature, heart sounds, and perfusion level. Perfusion level, for example, is can be a measurement of the **O2** content in the patient's tissues sensed with an optical sensor. Other types of sensed activity information of the patient by the sensor may also be used.

The control apparatus **181** can receive the sensed activity information from the sensing apparatus **186**. In one example, the control apparatus **181** can monitor and store sensed activity information of the patient received from the sensing apparatus **186**. The control apparatus **181** can determine a rate responsive pacing (RRP) profile (see, e.g., FIG. 5) to be provided to the implantable medical device **160** based on the sensed activity information received from the sensing apparatus **186**, as further described below.

The control apparatus **181** can determine and provide RRP profiles to the implantable medical device **160** based on sensed activity information from the sensing apparatus **186**. The implantable medical device **160** delivers cardiac pacing (i.e., rate responsive pacing) to the patient at a pacing rate corresponding to the RRP profile determined by the control apparatus **181**. For example, the RRP profile may increase the patient's paced heart rate based on an increase in activity

level, or no change in the activity level, and may decrease the patient's paced heart rate based on an undesirable patient condition. In one example, the pacing is selectively delivered during periods or durations of increased patient activity indicated by ongoing or periodically sensed activity information and is not delivered during periods or durations of rest indicated by a sensed resting heart rate. An increased activity level indicated by increased bodily movement of the patient for a period of time (e.g., 1-5 minutes) can indicate an activity event during which RRP is to be initiated. For example, an activity event can include a patient walking at a slow to brisk pace, as measured by an accelerometer as approximately 70-100 accelerometer counts over a one minute duration, translating to a walking speed of approximately one mile/hour. In one example, delivering RRP to the patient at the pacing rate corresponding to the RRP profile occurs when the sensed and monitored activity information is indicative of the activity level of the patient above a predetermined minimum that indicates an activity event. During therapy, the RRP profile can be adjusted based on additionally sensed activity information. In one example, the defined time period that a particular RRP profile is enabled can be sufficient for remodeling of the heart to occur, indicated by improved cardiac output or tissue perfusion. The control apparatus **181** can select and provide adjusted RRP profiles to the implantable medical device **160** based on sensed activity information from the sensing apparatus **186**, as further described below.

FIG. 5 is a graphical representation of some example RRP profiles useful in a cardiac therapy system in accordance with aspects of the present disclosure. A plurality of rate responsive profiles, such as the profiles indicated with lines **151a-151e**, can be determined by the control apparatus **181** of FIG. 4, for example. The plurality of RRP profiles **151a-151e** are representative only, and additional and/or other RRP profiles are understood to be within the scope of the present disclosure. Although illustrated linearly, any or all of the RRP profiles **151a-151e** can be stepped, curved, or any other shape or function. In one example, the RRP profiles increases steadily and then the increase may begin to taper where the HR saturates to an age adjusted maximal HR (i.e., 220 bpm—age). Maximal allowed HR may be lower if the patient on medication such as beta-blockers or I_f channel blockers (e.g. ivabradine). In some examples, RRP profiles can be tailored for each individual patient depending on their health status, medication usage, demographics (e.g., age, gender etc.) and lifestyle. In some examples, the RRP profiles can be automatically updated (e.g. every six months or a year) and adjusted in accordance with the changing health status of the patient. Regardless, the RRP profiles **151a-151e** include adjustments to the pacing rate such that the pacing rate is adjusted corresponding to the activity level of the patient based at least partially on the sensed activity information received by the control apparatus from the sensing apparatus (see also, e.g., FIG. 4).

With continued reference to FIG. 5, in one example, the RRP profiles **151a-151e** are each formed of pacing rates that increase as the patient's activity level increases. The RRP profile may be described as providing, or generating, a pacing rate based on the patient's activity level. In other words, the RRP profile may be described as pacing rate as a function of an activity level. In one example, the RRP profiles can be programmed into and/or developed by the control apparatus **181**. Each of the plurality of RRP profiles can include or generate a pacing rate that is increased as the activity level of the patient increases. The pacing rates can be aggressively increased, to increase the pacing rate to a

higher pacing rate more quickly, indicated by a sharp increase in the slope of RRP profile line (e.g., **151c**), or can be less aggressively increased, to increase the pacing rate to a smaller rate, indicated by a lesser slope of the RRP profile line (e.g., **151a**). The RRP profiles can be progressively scaled (e.g., increased) in terms of aggressiveness, with a more aggressive RRP profile having a greater increase in pacing rate over a determined activity level increase than a less aggressive RRP profile. For example, RRP **151b** increases more gradually over an increase in activity level from low level, **AL1**, to a moderate level, **AL3** than RRP **151d** over the same increase in activity level, **AL1** to **AL3**, as indicated in FIG. 5. The applied profiles could be increased, for example, from the less aggressive RRP profile **151a** to the more aggressive RRP profile **151e** over time, if there are no undesirable patient conditions present in the patient, as discussed further below with respect to FIGS. 6 and 7.

FIG. 6 illustrates an example method **200** of delivering RRP therapy in accordance with aspects of the present disclosure. The illustrative method **200** may include monitoring activity information related to an activity level of a patient at **202**. At **202**, monitoring activity information can include measuring, recording, and storing activity information of the patient, for example. The monitored activity information can be related to, or based on, the patient's physiological response of the patient's body indicative of movement or activity, such as exercise. The monitored activity information can include patient movement information including pulse wave velocity signals, electrocardiogram signals, intracardiac electrogram signals, blood pressure measurement, transthoracic impedance, subcutaneous impedance, temperature, heart sounds, and perfusion level, for example. The monitored activity information can be indicative of the current and past metabolic demand of the patient useful to determine adjustments to the RRP profile by the control apparatus.

After the monitoring **202** of the activity information (e.g., for a determined time period such as two weeks), the illustrative method **200** may initiate the delivery of RRP corresponding to a RRP profile at **204**. For example, one of the RRP profiles **151a-e** illustrated in FIG. 5 can be employed. The delivery **204** of RRP corresponding to the selected RRP profile can be applied with the medical device (e.g., IMD **160**) implanted into a patient to deliver the RRP therapy to the heart. In some examples, the IMD may deliver pacing pulses in accordance with one, or more than one, of the available RRP profiles over the course of the RRP therapy.

The method **200** may include adjusting the RRP profile **206** by evaluating the patient's activity information monitored one or both of before and during RRP **204**. Adjusting **206** or changing to a different RRP profile of the plurality of profiles delivered to the IMD may occur during, or simultaneous with, the monitoring **202** of the activity information of the patient over a duration of time after the delivery of RRP corresponding to a first, or initial, RRP profile. For example, the RRP may be initially delivered at a pacing rate corresponding to the RRP profile **151a** and adjusted to one of the other RRP **151b-151e** illustrated in FIG. 5 at a later time based on the sensed and monitored activity information of the patient. In some examples, perfusion level, blood pressure, temperature, and/or other activity information of the patient can be sensed in parallel with one another during the RRP therapy **200**. The RRP therapy **200** of the patient

can automatically monitor, deliver, and adjust of the RRP profiles at **202-206** which may be described as a closed-loop RRP therapy.

During, or simultaneous with, the delivery of RRP corresponding to the initially or currently delivered RRP profile at **204**, upcoming or future adjustment to the RRP are evaluated and determined at **206**. With the adjusting of the RRP profile at **206**, the activity information of the patient can concurrently, or subsequently, be monitored at **202**. If the monitored activity information at **202** indicates a change in the patient's activity level over time, then the control apparatus may determine that a different RRP profile (then the RRP profile currently delivered) is more suitable to deliver RRP at a suitable pacing rate for the patient via the IMD, and the RRP profile is adjusted at **206** accordingly.

The implantable medical device (e.g., electrode apparatus) can deliver cardiac pacing at pacing rates corresponding to each of the determined or generated RRP profiles. The RRP profile can be adjusted from a first RRP profile of a plurality of RRP profiles to a second RRP profile of the plurality of RRP profiles based on the sensed activity information indicating an increase in an activity level of the patient. The pacing electrodes can deliver cardiac pacing at the pacing rate corresponding to the RRP profile during activity events based on the sensed activity information. In one example, adjusting the RRP profile based on the monitored activity information includes periodically adjusting the RRP profile based on the monitored activity information after a time period, wherein the time period is greater than one day. In one example, adjusting the RRP profile based on the monitored activity information includes decreasing aggressiveness of the RRP profile in response to the monitored activity information indicating one or more undesirable patient conditions.

FIG. 7 illustrates a flow diagram of a method **300** of delivering rate responsive pacing therapy to a patient in accordance with aspects of the present disclosure. According to the illustrative example of method **300**, activity information of a patient is sensed at **302** during a time period (e.g., two weeks). In one example, during the sensing of the activity information at **302**, pacing is not delivered to the patient during the duration of the time period. The sensed activity information can provide a baseline of the patient's condition and activity level that can be useful in determining the RRP profile(s) to be applied during therapy. The sensed activity information related to the patient activity may include any sensed patient movement information including, but not limited to, pulse wave velocity signals, electrocardiogram signals, intracardiac electrogram signals, blood pressure measurement, and perfusion level.

In one example, the activity information is sensed, or acquired, by the sensing apparatus over a first defined time period, or first duration of time. The first defined time period can be hours, days, or weeks. For example, the defined time period can be selected to be greater than one day. The defined time period can be patient specific. Factors in determining the length, or duration, of the defined time period can include patient specific factors such as age, gender, lifestyle etc. and also baseline health status of the patient which can be either be qualitatively assessed (e.g. number of comorbidities) or quantitatively assessed (e.g. by doing a standard frailty assessment). Also, a device-based criterion can be used (e.g. **10,000** cumulative accelerometer counts) and duration in that case is adjusted automatically based on the patient's health status and lifestyle as an example. In one example, the activity information includes a first, or initial, activity information related to a first activity

level of the patient that is sensed by the sensing apparatus during the first, or initial, time period and determined by the control apparatus prior to delivering rate responsive pacing to the patient's heart with the implantable medical device. The first activity information can be used to establish a baseline of activity information of the patient prior to initiating pacing. The first, or baseline, activity information can be useful in determining an appropriate RRP profile to use with the initial RRP therapy. The first activity information, as well as subsequently monitored activity information, can be stored for reference and further determination of suitable RRP profiles to be employed in providing RRP to the patient during various phases of the therapy.

After the baseline activity information is sensed at **302**, an implanted medical device can initiate RRP corresponding to a RRP profile at **304**. In one example, the initiated RRP corresponds to an initial RRP profile determined based on the sensed activity information at **302**. In one example, the initiated RRP can be delivered at a pacing rate that is a slightly increased over the patient's pre-pacing, or base, heart rate. For example, initial pacing rate corresponding to the RRP profile delivered to the patient can be a percentage or a determined beats per minute increase over the base, or pre-paced, heart rate of the patient.

The illustrative method **300** may decrease the aggressiveness of the RRP due to, e.g., an undesirable patient condition. Thus, during RRP therapy, the patient may be monitored to determine whether an undesirable patient condition exists at **308**. An undesirable patient condition can indicate an adverse health state or condition. For example, the ST segment (from a sensed electrogram) may be monitored for ST elevation, and if the ST segment indicates ST elevation, then it may be determined that the patient has an undesirable patient condition. Further, for example, blood pressure may be monitored, and if blood pressure becomes too high or too low, then it may be determined that the patient has an undesirable patient condition. Further, for example, perfusion may be monitored, and if perfusion indicates that patient's blood oxygen saturation has dropped below a certain threshold (e.g. 75%) or greater than certain percentage from baseline (e.g. 15%), then it may be determined that the patient has an undesirable patient condition. Still further, for example, the patient may have one or more symptoms that may be undesirable such as, e.g., dyspnea/shortness of breath and/or increase in breathing rate as measured by device's impedance/EGM based respiration sensor ST segment elevation, abnormal/aperiodic breathing pattern, abnormal decrease or increase in temperature, abnormal increase or decrease in device measured transthoracic impedance, appearance of abnormal heart sounds (e.g. S3 and S4 heart sounds), which may be suggestive of abnormal fluid shifts/accumulation, onset of atrial arrhythmias, increase in PVC burden, etc., and such symptoms may be acquired to manual entry (e.g., patient input). If such symptoms are undesirable, then it may be determined that the patient has an undesirable effect from the RRP related elevation in heart rate resulting in an undesirable patient condition. In one example, the control apparatus can determine the occurrence of an undesirable condition at **308** using, or based on, the sensed activity information of the patient that is being sensed by the sensing apparatus at **302**.

In response to the determination at **308** that an undesirable patient condition is present, the illustrative method **300** may adjust the RRP profile at **317** to a new RRP profile that is less aggressive than the RRP profile initially applied (see, e.g., RRP profiles **151a-e** illustrated in FIG. 4). For example, the new RRP profile may provide lower pacing rates at similar

activity levels than the previously-used RRP profile. Thus, in other words, the patient's heart will not be paced as rapidly, or quickly, has previously paced at the same activity levels to, e.g., reduce or eliminate the previously-determined undesirable patient conditions at **308**.

Additionally, if the RRP profile was already the least aggressive at **318** as provided by the method **300**, then the method **300** may stop, e.g., so as to cease any further adjustment to the RRP profile. More specifically, after the adjustment to the RRP profile at **317**, the method **300** may determine whether the adjusted RRP profile is at the lowest level or is the least aggressive RRP profile available at **318**. In response to determining that the applied RRP profile is least aggressive, further adjustments to the RRP profile are stopped at **319**. Alternatively, if the RRP profile being applied is not the least aggressive, the patient may be again be monitored to determine whether an undesirable patient condition exists at **308**. If the patient experiences an undesirable patient condition at the least aggressive RRP profile, the RRP therapy may be stopped for a duration (e.g., one week, two weeks, a month, etc.) and then re-initiated in further attempts to assist the patient with the RRP therapy.

In response to a determination that an undesirable patient condition is not present at **308**, activity information is monitored during delivery of RRP corresponding to the RRP profile at **310**. In one example, the monitored activity information may include any of the sensed patient movement information discussed above with respect to the sensed activity information at **302**. For example, the monitored activity information can relate to sensed patient information including, but not limited to, accelerometer signals, pulse wave velocity signals, electrocardiogram signals, intracardiac electrogram signals, blood pressure measurement, and perfusion level.

For example, the control apparatus can monitor a second sensed activity information related to a second activity level of the patient during RRP corresponding to the initial RRP profile. The second activity information is determined with sensed information acquired by the sensing apparatus over a second time period. The second time period can be of an equal length of time, or a different length of time, than the first time period. Similarly, as the therapy **300** continues, subsequent, or additional, activity information and/or subsequent, or additional, time periods can also be sensed and monitored and the first and second activity information and time periods are merely illustrative and not to be viewed as limiting.

After receiving the sensed and monitored activity information of the patient, a change to the activity information can be determined at **312**. For example, the method **300** may determine whether the patient's activity level has increased, decreased, or remained the same. In one example, change in the activity information at **312** can include comparing the sensed activity information of **302** (e.g., first activity information) to the monitored activity information during RRP corresponding to the RRP profile of **310** (e.g., second activity information). In other words, the control apparatus can compare activity information related to the patient's activity levels over the first and second defined time periods. For example, activity information such as accelerometer rates can be sensed and stored during each of the time periods, respectively, and the highs, lows and/or averages can be compared. The compared activity information can be useful in assessing the suitability of the RRP profile applied to the patient. For example, an increase in the patient's activity level indicated by the activity information can be indicative of improvement to the patient's cardiac health.

The illustrative method **300** can use changes in the activity information to determine whether the selected (e.g., applied) RRP profile is the most aggressive RRP profile by the system and/or provided for the specific patient receiving RRP therapy. For example, the RRP profile can be increased the most aggressive RRP profile (e.g., **151e** of FIG. **5**) but will not exceed the maximal heart rate for the patient (i.e., **220** minus age). In some examples, the pacing applied at the most aggressive RRP profile will be 10%-20% below the maximal heart rate for the patient. In response to a change in the patient's activity information (e.g., increase in accelerometer rate) determined at **312**, the method accesses whether the applied RRP profile is the most aggressive for the patient at **315**. It can be desirable to apply the most aggressive RRP profile for the patient to provide heart rate pacing to the patient at in order to maximize the heart functionality of the patient. In response to a determination that the RRP profile is the most aggressive for the patient at **315**, the method **300** may return to monitoring whether an undesirable patient condition exists at **308**.

In response to a determination that the RRP profile being applied is not the most aggressive available for the patient at **315**, the illustrative method **300** may adjust the RRP profile at **316** to a new RRP profile that is more aggressive than the RRP profile currently, or previously, being applied (see, e.g., RRP profiles **151a-e** illustrated in FIG. **5**). For example, an adjusted RRP profile can be selected that is more aggressive than the RRP profile being currently provided in response to the determination that the RRP profile being applied to the patient is not the most aggressive that can be applied to the patient having an increase in activity level. The control apparatus can adjust the RRP profile until a maximum, or most, aggressiveness RRP profile is determined at **315**. For example, the adjusted RRP profile may provide higher pacing rates at similar activity levels than the previously applied RRP profile. In this manner, the patient's heart can be paced more rapidly, or quickly, than previously paced at the same activity levels. After the RRP profile is adjusted to a more aggressive RRP profile at **316**, the patient may again, or continue to, be monitored to determine whether an undesirable patient condition exists during pacing of the patient's heart at the more aggressive RRP profile at **308**.

In some examples, no change to the monitored activity information of the patient is determined to have occurred over the defined time period at **312**. In response to the determination of no change to the activity information of the patient at **312**, a determination can be made as to whether the most aggressive RRP profile has been applied at **314**. In one example, if the method **300** determines at **314** that the most aggressive RRP profile has not been applied, the RRP profile may be adjusted to a more aggressive RRP profile. For example, further adjustment to increased pacing rates corresponding to the adjusted RRP profile may be useful to increase blood flow through the heart. After the RRP profile is adjusted to a more aggressive RRP profile at **316**, the patient may again, or continue to, be monitored to determine whether an undesirable patient condition exists during pacing of the patient's heart at the more aggressive RRP profile at **308**.

In other examples, after determining that there is no change in activity information at **312**, the method **300** can determine that the most aggressive RRP profile is applied to the patient at **314**. As a result, the method **300** may stop, or cease, any further adjustment to the RRP profile at **320**. In

some examples, further adjustments to the RRP profile will be reassessed with the RRP therapy techniques after a period of time (e.g., one week to one month).

As indicated above and with reference to the method **300** of FIG. **7**, the pacing rate can be evaluated and increased corresponding one or more of the plurality of RRP profiles over multiple defined periods, as determined by the control apparatus based on the activity information of the patient and other determinations. In other words, the method **300** can be a closed-loop method that delivers adjusted RRP profiles to the IMD based on the sensed and monitored information. In one example, the method **300** can be employed to gradually transition the patient to higher pacing rates corresponding to a more aggressive RRP profile. The method **300** can adjust to a more or less aggressive RRP profile, or maintain the already selected and applied RRP profile, in accordance to the aggressiveness determinations and the presence of undesirable patient condition(s).

In one example, the method can include providing a plurality of RRP profiles ranging from a least aggressive RRP profile to a most aggressive RRP profile. In one example, adjusting the RRP profile can include selecting one of the plurality of RRP profiles based on the monitored activity information. In one example, adjusting the RRP profile based on the monitored activity information can include increasing aggressiveness of the RRP profile in response to the monitored activity information indicating an increase in the activity level of the patient. In one example, adjusting the RRP profile based on the monitored activity information can include increasing aggressiveness of the RRP profile to a maximum aggressiveness RRP profile. In one example, adjusting the RRP profile based on the monitored activity information can include increasing aggressiveness of the RRP profile in response to the monitored activity information indicating a lack of increase in the activity level of the patient.

The method **300** can include multiple RRP profile adjustments that can be aggregated over multiple steps **302-320** occurring over multiple durations until the least or most aggressive RRP profile is determined for the patient. The control apparatus continues to provide adjusted RRP profiles to the implantable medical device based on continued sensed activity information from the sensing apparatus. The control apparatus can determine and provide one or more RRP profiles (see, e.g., FIG. **5**) to the implantable medical device for RRP of the patient during the course (e.g., weeks, months, years) of the therapy including a plurality of defined time periods. Additional determinations and monitoring are continued until the control apparatus determines that either the least or most aggressive RRP profile for that patient is being applied, and further adjustments are stopped at **319** or **320** as described above. In one or more examples, the rate responsive pacing therapy may produce cardiac remodeling in the patient. In some examples, the illustrative method **300** may continue determining and adjusting the RRP profile being applied to cause, and during, remodeling of the heart.

Although the present disclosure has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes can be made in form and detail without departing from the spirit and scope of the present disclosure.

EMBODIMENTS

Embodiment 1: A method of delivering rate responsive pacing therapy comprising:

monitoring activity information related to an activity level of a patient;

delivering a rate responsive pacing (RRP) to the patient at a pacing rate corresponding to a RRP profile, wherein the RRP profile generates the pacing rate based on the activity information; and

adjusting the RRP profile based on the monitored activity information.

Embodiment 2: The method as set forth in embodiment 1, further comprising:

providing a plurality of RRP profiles ranging from a least aggressive RRP profile to a most aggressive RRP profile,

wherein adjusting the RRP profile comprises selecting one of the plurality of RRP profiles based on the monitored activity information.

Embodiment 3: The method as set forth in one of embodiments 1-2, wherein adjusting the RRP profile based on the monitored activity information comprises increasing aggressiveness of the RRP profile in response to the monitored activity information indicating an increase in the activity level of the patient.

Embodiment 4: The method as set forth in embodiment 3, wherein adjusting the RRP profile based on the monitored activity information comprises increasing aggressiveness of the RRP profile to a maximum aggressiveness RRP profile.

Embodiment 5: The method as set forth in one of embodiments 1-4, wherein adjusting the RRP profile based on the monitored activity information comprises increasing aggressiveness of the RRP profile in response to the monitored activity information indicating a lack of increase in the activity level of the patient.

Embodiment 6: The method as set forth in one of embodiments 1-5, wherein monitoring activity information comprises:

determining a first monitored activity information prior to delivering the rate responsive pacing, and

determining a second monitored activity information after delivering the rate responsive pacing,

wherein adjusting the RRP profile based on the monitored activity information comprises comparing the first monitored activity information to the second monitored activity information.

Embodiment 7: The method as set forth in one of embodiments 1-6, wherein delivering RRP to the patient at the pacing rate corresponding to the RRP profile occurs when the monitored activity information is indicative of the activity level of the patient is above a minimum.

Embodiment 8: The method as set forth in one of embodiments 1-7, wherein adjusting the RRP profile based on the monitored activity information comprises periodically adjusting the RRP profile based on the monitored activity information after a time period, wherein the time period is greater than one day.

Embodiment 9: The method as set forth in one of embodiments 1-8, wherein the monitored activity information comprises at least one of patient movement information, pulse wave velocity signals, electrocardiogram signals, intracardiac electrogram signals, blood pressure measurement, transthoracic impedance, subcutaneous impedance, temperature, heart sounds, and perfusion level.

Embodiment 10: The method as set forth in one of embodiments 1-9, wherein adjusting the RRP profile based on the monitored activity information comprises decreasing

aggressiveness of the RRP profile in response to the monitored activity information indicating an undesirable patient condition.

Embodiment 11: An implantable medical device comprising:

a sensing apparatus comprising a sensor to sense activity information of a patient;

a control apparatus comprising processing circuitry to select a rate responsive pacing (RRP) profile based on the sensed activity information received from the sensing apparatus; and

an electrode apparatus comprising a plurality of pacing electrodes, the electrode apparatus operably coupled to the control apparatus, the electrode apparatus to deliver rate responsive pacing to the patient at a pacing rate corresponding to the RRP profile,

wherein control apparatus is to adjust the RRP profile based on the sensed activity information.

Embodiment 12: The device as set forth in embodiment 11, wherein the pacing electrodes are to deliver rate responsive pacing at the pacing rate corresponding to the RRP profile during activity events based on the sensed activity information.

Embodiment 13: The device as set forth in one of embodiments 11-12, wherein the control apparatus is to adjust the RRP profile based on the sensed activity information indicating an increase in the patient's activity and a maximum aggressiveness is not exceeded.

Embodiment 14: The device as set forth in one of embodiments 11-13, wherein the electrode apparatus is to deliver rate responsive pacing corresponding to a plurality of RRP profiles, wherein the RRP profile is adjusted from a first RRP profile of a plurality of RRP profiles to a second RRP profile of the plurality of RRP profiles based on the sensed activity information indicating an increase in an activity level of the patient.

Embodiment 15: A therapy system comprising:

a sensing apparatus comprising a sensor to sense activity information of a patient;

a control apparatus comprising processing circuitry, the control apparatus operably coupled to the sensing apparatus, the control apparatus configured to:

monitor sensed activity information of the patient,

determine a first activity information of a patient related to a first activity level of the patient,

determine a second activity information related to a second activity level of the patient,

compare the first activity information to the second activity information, and

determine a rate responsive pacing (RRP) profile based on the compared activity information; and

an implantable medical device comprising pacing electrodes, the implantable medical device operably coupled to the control apparatus, the electrodes to deliver rate responsive pacing (RRP) to the patient at a pacing rate corresponding to the determined RRP profile.

Embodiment 16: The system as set forth in embodiment 15, wherein the control apparatus is to provide adjusted RRP profiles to the implantable medical device based on sensed activity information from the sensing apparatus.

Embodiment 17: The system as set forth in embodiment 16, wherein the control apparatus is to determine a less aggressive RRP profile if the sensed activity information indicates an undesired patient condition, and wherein the pacing rate delivered by the electrodes of the implantable medical device is adjusted to correspond to the less aggressive RRP profile.

Embodiment 18: The system as set forth in one of embodiments 15-17, wherein the control apparatus is to provide an adjusted RRP profile that is more aggressive than the RRP profile to the implantable medical device in response to an increase in an activity level of the patient indicated by the sensed activity information from the sensor apparatus.

Embodiment 19: The system as set forth in one of embodiments 15-18, wherein the sensing apparatus is to sense at least one of patient movement information, pulse wave velocity signals, electrocardiogram signals, intracardiac electrogram signals, blood pressure measurement, transthoracic impedance, subcutaneous impedance, temperature, heart sounds, and perfusion level.

Embodiment 20: The system as set forth in one of embodiments 15-19, wherein the implantable medical device comprises at least one of the control apparatus and the sensing apparatus.

The invention claimed is:

1. An implantable medical device comprising:
 - a sensing apparatus comprising a sensor to sense activity information of a patient;
 - a control apparatus comprising processing circuitry to select a rate responsive pacing (RRP) profile from a plurality of RRP profiles ranging from a least aggressive RRP profile to a most aggressive RRP profile based on the sensed activity information received from the sensing apparatus, wherein each of the plurality of RRP profiles generates a pacing rate based on the sensed activity information over a same range of sensed activity information; and
 - an electrode apparatus comprising a plurality of pacing electrodes, the electrode apparatus operably coupled to the control apparatus, the electrode apparatus to deliver rate responsive pacing to the patient at the pacing rate generated by the selected RRP profile, wherein selecting the RRP profile from the plurality of RRP profiles comprises selecting a more aggressive RRP profile from the plurality of RRP profiles than the previously selected RRP profile based on the sensed activity information indicating an increase in the patient's activity and the most aggressive RRP profile of the plurality of profiles is not already selected.
2. The device of claim 1, wherein the pacing electrodes deliver rate responsive pacing at the pacing rate generated by the selected RRP profile during activity events based on the sensed activity information.
3. The device of claim 1, wherein selecting the RRP profile from the plurality of RRP profiles comprises selecting a less aggressive RRP profile from the plurality of RRP profiles than the previously selected RRP profile based on the sensed activity information indicating an undesirable patient condition.
4. A therapy system comprising:
 - a sensing apparatus comprising a sensor to sense activity information of a patient;
 - a control apparatus comprising processing circuitry, the control apparatus operably coupled to the sensing apparatus, the control apparatus configured to:
 - monitor sensed activity information of the patient,
 - determine a first activity information of a patient related to a first activity level of the patient,
 - determine a second activity information related to a second activity level of the patient,
 - compare the first activity information to the second activity information,

determine a rate responsive pacing (RRP) profile from a plurality of RRP profiles ranging from a least aggressive RRP profile to a most aggressive RRP profile based on the compared activity information, wherein each of the plurality of RRP profiles generates a pacing rate based on the sensed activity information over a same range of sensed activity information, and

determine a more aggressive RRP profile of the plurality of RRP profiles than the previously determined RRP profile in response to an increase in an activity level of the patient indicated by the sensed activity information from the sensor apparatus; and
 an implantable medical device comprising pacing electrodes, the implantable medical device operably coupled to the control apparatus, the pacing electrodes to deliver rate responsive pacing (RRP) to the patient at the pacing rate generated by the determined RRP profile.

5. The system of claim 4, wherein the control apparatus is further configured to determine a less aggressive RRP profile of the plurality of RRP profiles than the previously determined RRP profile if the sensed activity information indicates an undesired patient condition.

6. The system of claim 4, wherein the sensing apparatus senses one or more of patient movement information, pulse wave velocity signals, electrocardiogram signals, intracardiac electrogram signals, blood pressure measurement, transthoracic impedance, subcutaneous impedance, temperature, heart sounds, and perfusion level.

7. The system of claim 4, wherein the implantable medical device comprises at least one of the control apparatus and the sensing apparatus.

8. A method of delivering rate responsive pacing therapy comprising:

- monitoring activity information related to an activity level of a patient;

- selecting a rate responsive pacing (RRP) profile from a plurality of RRP profiles ranging from a least aggressive RRP profile to a most aggressive RRP profile based on the monitored activity information, wherein each of the plurality of RRP profiles generates a pacing rate based on the sensed activity information over a same range of sensed activity information; and

- delivering a rate responsive pacing (RRP) to the patient at the pacing rate generated by the selected RRP profile, wherein the selected RRP profile generates the pacing rate based on the activity information,

- wherein selecting the RRP profile from the plurality of RRP profiles based on the monitored activity information comprises selecting a more aggressive RRP profile from the plurality of RRP profiles than the previously selected RRP profile in response to the monitored activity information indicating an increase in the activity level of the patient, and the most aggressive RRP profile of the plurality of RRP profiles is not already selected.

9. The method of claim 8, wherein selecting the RRP profile from the plurality of RRP profiles based on the monitored activity information comprises selecting the most aggressive RRP profile from the plurality of RRP profiles.

10. The method of claim 8, wherein monitoring activity information comprises:

- determining a first monitored activity information prior to delivering the rate responsive pacing, and

- determining a second monitored activity information after delivering the rate responsive pacing,

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wherein selecting the RRP profile from the plurality of RRP profiles based on the monitored activity information comprises comparing the first monitored activity information to the second monitored activity information.

11. The method of claim 8, wherein delivering RRP to the patient at the pacing rate corresponding to the selected RRP profile occurs when the monitored activity information is indicative of the activity level of the patient is above a minimum.

12. The method of claim 8, wherein selecting the RRP profile from the plurality of RRP profiles based on the monitored activity information comprises periodically selecting the RRP profile based on the monitored activity information after a time period, wherein the time period is greater than one day.

13. The method of claim 8, wherein the monitored activity information comprises at least one of patient movement

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information, pulse wave velocity signals, electrocardiogram signals, intracardiac electrogram signals, blood pressure measurement, transthoracic impedance, subcutaneous impedance, temperature, heart sounds, and perfusion level.

5 14. The method of claim 8, wherein selecting the RRP profile from the plurality of RRP profiles based on the monitored activity information comprises selecting a less aggressive RRP profile from the plurality of RRP profiles than the previously selected RRP profile in response to the
10 monitored activity information indicating an undesirable patient condition.

15 15. The device of claim 1, wherein the plurality of RRP profiles are programmed into the control apparatus.

16. The device of claim 1, wherein the plurality of RRP profiles are developed by the control apparatus.

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